# 24th Annual National Conference on Managing Environmental Quality Systems

**8:30 – 12:00 TUESDAY, APRIL 12TH - A.M. Stockholder Meetings**

**12:00 – 4:30 TUESDAY, APRIL 12TH**
**Opening Plenary** (Salons A-H)

- Opening Address
    - Reggie Cheatham, Director, OEI Quality Staff, EPA
    - Linda Travers, Principal Deputy Assistant Administrator, OEI, EPA
- Invited Speakers
    - Tom Huetteman, Deputy Assistant Regional Administrator, EPA Region 9
    - John Robertus, Executive Officer of San Diego Regional Water Quality Control Board, Region 9
- Keynote Address
    - Thomas Redman, President, Navesink Consulting Group
- Panel Sessions
- **Value of the Data Quality Act—Perspectives from OMB, Industry, and EPA (VDQA)**
    - Nancy Beck, OMB
    - Jamie Conrad, American Chemistry Council
    - Reggie Cheatham, Director, OEI Quality Staff, EPA
- **Wadeable Streams: Assessing the Quality of the Nation's Streams (WS)**
    - Margo Hunt, Panel Moderator
    - Mike Shapiro, Deputy Assistant Administrator, Office of Water
    - Steve Paulsen, Research Biologist, ORD

**8:30 – 10:00 WEDNESDAY, APRIL 13TH**
**Environmental Measures (EM)** (Salons A-C) *Chair: L. Bradley, EPA*

- Data Error Reduction by Automation throughout the Data Workflow Process (A. Gray, EarthSoft, Inc.)
- Analytical Approaches to Meeting New Notification Levels for Organic Contaminants in Calif. (D.Wijekoon, Calif. DHS)
- Streamlining Data Management and Communications for the Former Walker AFB Project (R. Amano, Lab Data Consultants, Inc.)

**Quality System Implementation in the Great Lakes Program (QSI-GLP)** (Salon D) *Chair: M. Cusanelli, EPA*

- GLNPO's Quality System Implementation for the New "Great Lakes Legacy Act for Sediment Remediation"(L. Blume, EPA)
- Black Lagoon Quality Plan Approval by GLNPO, MDEQ, ERRS, and USACE (J. Doan, Environmental Quality Management, Inc.)
- Remediation of the Black Lagoon Trenton Channel . . . Postdredging Sampling & Residuals Analysis (J. Schofield, CSC)

**Quality Systems Models (QSM)** (Salons F-H) *Chair: G. Johnson, EPA*

- Improving E4 Quality System Effectiveness by Using ISO 9001: 2000 Process Controls (C. Hedin, Shaw Environmental)

**Applications of Novel Techniques to Environmental Problems (ANTEP)** (Salon E) *Chair: B. Nussbaum, EPA*

- On Some Applications of Ranked Set Sampling (B. Sinha, University of Maryland)
- Combining Data from Many Sources to Establish Chromium Emission Standards (N. Neerchal, University of Maryland)
- Estimating Error Rates in EPA Databases for Auditing Purposes (H. Lacayo, Jr., EPA)
- Spatial Population Partitioning Using Voronoi Diagrams For Environmental Data Analysis (A. Singh, UNLV)

**Ambient Air Session I (Sierra 5&6)** *Chair: M.Papp, EPA*

- Changes and Improvements in the Ambient Air Quality Monitoring Program Quality System (M. Papp, EPA)
- Guidance for a New Era of Ambient Air Monitoring (A. Kelley, Hamilton County DES)
- Environmental Monitoring QA in Indian Country (M. Ronca-Battista, Northern Arizona University)
- Scalable QAPP IT Solution for Air Monitoring Programs (C. Drouin, Lake Environmental Software)

**10:30 – 12:00 WEDNESDAY, APRIL 13TH**

**Environmental Laboratory Quality Systems (ELQS)** (Salons A-C) *Chair: L. Bradley, EPA*

- A Harmonized National Accreditation Standard: The Next Step for INELA Field Activities (D. Thomas, Professional Service Industries, Inc.)
- Development of a Comprehensive Quality Standard for Environmental Laboratory Accreditation (J. Parr, INELA)
- Advanced Tracking of Laboratory PT Performance and Certification Status with Integrated Electronic NELAC-Style Auditing Software (T. Fitzpatrick, Lab Data Consultants, Inc.)

**Performance Metrics (PM)** (Salon D) *Chair: L. Doucet, EPA*

- Formulating Quality Management Metrics for a State Program in an Environmental Performance Partnership Agreement (P. Mundy, EPA)
- How Good Is "How Good Is?" (Measuring QA) (M. Kantz, EPA)
- Performance-Based Management (J. Santillan, US Air Force)

**Quality Assurance Plan Guidance Initiatives (QAPGI)** (Salons F-H) *Chair: A. Batterman, EPA*

- A CD-ROM Based QAPP Preparation Tool for Tribes (D. Taylor, EPA)
- Military Munitions Response Program Quality Plans (J. Sikes, U.S. Army)

**Ask a Statistician: Panel Discussion** (Salon E) *Moderator: B. Nussbaum, EPA* Panelists:

- Mike Flynn, Director, Office of Information Analysis and Access, OEI, EPA
- Reggie Cheatham, Director, Quality Staff, OEI, EPA
- Tom Curran, Chief Information Officer, OAQPS, EPA
- Diane Harris, Quality Office, Region 7, EPA
- Bill Hunt, Visiting Senior Scientist, North Carolina State University (NCSU)
- Rick Linthurst, OIG, EPA

**Ambient Air Session II** (Sierra 5&6) *Chair: M. Papp, EPA*

- National Air Toxics QA System and Results of the QA Assessment (D. Mikel, EPA)
- Technical System Audits (TSAs) and Instrument Performance Audits (IPAs) of the National Air Toxics Trends Stations (NATTS) and Supporting Laboratories (S. Stetzer Biddle, Battelle)
- Interlaboratory Comparison of Ambient Air Samples (C. Pearson, CARB)
- Developing Criteria for Equivalency Status for Continuous PM2.5 Samplers (B. Coutant, Battelle)

**1:00 – 2:30 WEDNESDAY, APRIL 13TH**

**Environmental Laboratory Quality (ELQ)** (Salons A-C) *Chair: L. Doucet, EPA*

- Environmental Laboratory Quality Systems: Data Integrity Model and Systematic Procedures (R. DiRienzo, DataChem Laboratories, Inc.)
- The Interrelationship of Proficiency Testing, Interlaboratory Statistics and Lab QA Programs (T. Coyner, Analytical Products Group, Inc.)
- EPA FIFRA Laboratory Challenges and Solutions to Building a Quality System in Compliance with International Laboratory Quality Standard ISO 17025 (A. Ferdig, Mich. Dept. of Agriculture)

**Performance—Quality Systems Implementation (P-QSI)** (Salon D) *Chair: A. Belle, EPA*

- Implementing and Assessing Quality Systems for State, Tribal, and Local Agencies (K. Bolger, D. Johnson, L. Blume, EPA)

**1:00 – 2:30 WEDNESDAY, APRIL 13TH (continued)**

**Quality Initiatives in the EPA Office of Environmental Information (QI-OEI)** (Salons F-H) *Chair: J. Worthington, EPA*

- Next Generation Data Quality Automation in EPA Data Marts (P. Magrogan, Lockheed)
- The Design and Implementation of a Quality System for IT Products and Services (J. Scalera, EPA)
- Data Quality is in the Eyes of the Users: EPA's Locational Data Improvement Efforts (P. Garvey, EPA)

**A Win-Win-Win Partnership for Solving Environmental Problems (W3PSEP)** (Salon E) *Co-Chairs: W. Hunt, Jr. and K. Weems, NCSU*

- Overview of Environmental Statistics Courses at NCSU (B. Hunt, NCSU Statistics Dept.)
- Overview of the Environmental Statistics Program at Spelman College (N. Shah, Spelman)
- Student presentations: H. Ferguson and C. Smith of Spelman College; C. Pitts, B. Stines and J. White of NCSU

**Ambient Air Session III** (Sierra 5&6) *Chair: M. Papp, EPA*

- Trace Gas Monitoring for Support of the National Air Monitoring Strategy (D. Mikel, EPA)
- Comparison of the Proposed Versus Current Approach to Estimate Precision and Bias for Gaseous Automated Methods for the Ambient Air Monitoring Program (L. Camalier, EPA)
- Introduction to the IMPROVE Program's New Interactive Web-based Data Validation Tools (L. DeBell, Colorado State University)
- The Role of QA in Determination of Effects of Shipping Procedures for PM2.5 Speciation Filters (D. Crumpler, EPA)

**3:00 – 4:30 WEDNESDAY, APRIL 13TH**

**Topics in Environmental Data Operations (TEDO)** (Salons A-C) *Chair: M. Kantz, EPA*

- Ethics in Environmental Operations: It's More Than Just Lab Data (A. Rosecrance, Laboratory Data Consultants, Inc.)
- QA/QC of a Project Involving Cooperative Agreements, IAGs, Agency Staff and Contracts to Conduct the Research (A. Batterman, EPA)
- Dealing with Fishy Data: A Look at Quality Management for the Great Lakes Fish Monitoring Program (E. Murphy, EPA)

**Quality System Development (QSD)** (Salon D) *Chair: A. Belle, EPA*

- Development of a QA Program for the State of California (B. van Buuren, Van Buuren Consulting, LLC)
- Integrating EPA Quality System Requirements with Program Office Needs for a Practical Approach to Assuring Adequate Data Quality to Support Decision Making (K. Boynton, EPA)
- Introducing Quality System Changes in Large Established Organizations (H. Ferguson, EPA)

**Auditor Competence (AC)** (Salons F-H) *Chair: K. Orr, EPA*

- Determining the Competence of Auditors (G. Johnson, EPA)

**To Detect or Not Detect—What Is the Problem? (TDND)** (Salon E) *Chair: J. Warren, EPA*

- A Bayesian Approach to Measurement Detection Limits (B. Venner)
- The Problem of Statistical Analysis with Nondetects Present (D. Helsel, USGS)
- Handling Nondetects Using Survival Anal.(D. Helsel, USGS)
- Assessing the Risk associated with Mercury: Using ReVA's Webtool to Compare Data, Assumptions and Models (E. Smith, EPA)

**Ambient Air Session IV** (Sierra 5&6) *Chair: M. Papp, EPA*

- Status and Changes in EPA Infrastructure for Bias Traceability to NIST (M. Shanis, EPA)
- Using the TTP Laboratory at Sites with Higher Sample Flow Demands (A. Teitz, EPA )

**5:00 – 6:00 PM WEDNESDAY, APRIL 13TH**

**EPA SAS Users Group Meeting** Contact: Ann Pitchford, EPA

**8:30 – 10:00 THURSDAY, APRIL 14TH**

**Evaluating Environmental Data Quality (EEDQ)** *(Salons A-C) Chair: M. Kantz, EPA*

- QA Documentation to Support the Collection of Secondary Data (J. O'Donnell, Tetra Tech, Inc.)
- Staged Electronic Data Deliverable: Overview and Status (A. Mudambi, EPA)
- Automated Metadata Reports for Geo-Spatial Analyses (R. Booher, INDUS Corporation)

**Satellite Imagery QA (SI-QA)** (Salon D) *Chair: M. Cusanelli, EPA*

- Satellite Imagery QA Concerns (G. Brilis and R. Lunetta, EPA)

**Information Quality Perspectives (IQP)** (Salons F-H) *Chair: J. Worthington, EPA*

- A Body of Knowledge for Information and Data Quality (J. Worthington, L. Romero Cedeno, EPA)
- Information as an Environmental Technology – Approaching Quality from a Different Angle (K. Hull, Neptune and Co.)

**To Detect or Not Detect—What Is the Answer? (TDND)** (Salon E) *Chair: A. Pitchford, EPA, Co-Chair: W. Puckett, EPA*

- Using Small Area Analysis Statistics to Estimate Asthma Prevalence in Census Tracts from the National Health Interview Survey (T. Brody, EPA)
- Logistical Regression and QLIM Using SAS Software (J. Bander, SAS)
- Bayesian Estimation of the Mean in the Presence of Nondetects (A. Khago, University of Nevada)

**Ambient Air Workgroup Meeting** (Sierra 5&6) *Contact: Mike Papp, EPA*
NOTE: This is an all-day, closed meeting.

**10:30 – 12:00 THURSDAY, APRIL 14TH**

**Environmental Data Quality (EDQ)** (Salons A-C) *Chair: V. Holloman, EPA*

- Assessing Environmental Data Using External Calibration Procedures (Y. Yang, CSC)
- Groundwater Well Design Affects Data Representativeness: A Case Study on Organotins (E. Popek, Weston Solutions)

**Information Quality and Policy Frameworks (IQPF)** (Salons F-H) *Chair: L. Doucet, EPA*

- Modeling Quality Management System Practices to an Organization's Performance Measures (J. Worthington, L. Romero Cedeño, EPA)
- Development of a QAPP for Agency's Portal (K. Orr, EPA)
- Discussion of Drivers and Emerging Issues, Including IT, That May Result in Revisions to EPA's Quality Order and Manual (R. Shafer, EPA)

**Office of Water; Current Initiatives (OW)** (Salon D) *Chair: D. Sims, EPA*

- Whole Effluent Toxicity--The Role of QA in Litigation (M. Kelly, EPA, H. McCarty, CSC)
- Review of Data from Method Validation Studies: Ensuring Results Are Useful Without Putting the Cart Before the Horse (W. Telliard, EPA, H. McCarty, CSC)
- Detection and Quantitation Concepts: Where Are We Now? (Telliard, Kelly, and McCarty)

**Sampling Inside, Outside, and Under (SIOU)** (Salon E) *Chair: J. Warren, EPA*

- VSP Software: Designs and Data Analyses for Sampling – Contaminated Buildings (B. Pulsipher, J. Wilson, Pacific Northwest National Laboratory , R. O. Gilbert)
- Incorporating Statistical Analysis for Site Assessment into a Geographic Information System (D. Reichhardt, MSE Technology Applications, Inc.)
- The OPP's Pesticide Data Program Environmental Indicator Project (P. Villanueva, EPA)

**1:00 – 2:30 THURSDAY, APRIL 14TH**

**Information Management** (Salons A-C) *Chair: C. Thoma, EPA*

- Achieve Information Management Objectives by Building and Implementing a Data Quality Strategy (F. Dravis, Firstlogic)

**UFP Implementation** (Salon D) *Chair: D. Sims, EPA*

- Implementing the Products of the Intergovernmental DQ Task Force: The UFP QAPP (R. Runyon, M. Carter, EPA)
- Measuring Performance: The UFP QAPP Manual (M. Carter, EPA, C. Rastatter, VERSAR)

**Quality Systems Guidance and Training Developments (QSG)** (Salons F-H) *Chair: M. Kantz, EPA*

- A Sampling and Analysis Plan Guidance for Wetlands Projects (D. Taylor, EPA )
- My Top Ten List of Important Things I Do as an EPA QA and Records Manager (T. Hughes, EPA)
- I'm Here---I'm Free----Use Me! Use Me!—Secondary Use of Data in Your Quality System (M. Kantz, EPA)

**Innovative Environmental Analyses (IEA)** (Salon E) *Chair: M. Conomos, EPA*

- Evaluation of Replication Methods between NHANES 1999-2000 and NHANES 2001-2002 (H. Allender, EPA)
- Assessment of the Relative Importance of the CrEAM Model's Metrics (A. Lubin, L. Lehrman, and M. White, EPA)
- Statistical Evaluation Plans for Compliance Monitoring Programs (R. Ellgas, Shaw Environmental, Inc.; J. Shaw, EMCON/OWT, Inc.)

# Ethics in Environmental Operations – Its More Than Just Data

Ann Rosecrance

EPA Quality Management Meeting

San Diego, CA

April 13, 2005

## EPA Quality Management Goal

- Data of the quality needed for environmental decisions
  - Correct data leads to good decisions
  - Incorrect data can result in incorrect decisions and unacceptable risk to human health and the environment and unnecessary expenditure of funds

"The accuracy and truthfulness of environmental data is a cornerstone for environmental enforcement and compliance, and is essential to the protection of public health and the environment." EPA Criminal Enforcement

*"In God we trust, all others bring data." Dr. Edward Deming*

*"Give just weight and full measure." the Koran*

# Objective

- Emphasize the need for ethics in all areas of environmental operations so that good decisions can be made
- Reminder of our role as Quality Ethics Leaders for the next generation
  - Let's learn from the history of fraud in the environmental field and the news everyday about occurrences of fraud
  - Let's teach others the "rules" and that is doesn't pay to break the rules
  - Resist any temptation to cheat, deceive or mislead others for personal gain or to cover up laziness, lack of knowledge and poor performance
- Consider the Question: Is it possible to be both ethical and successful?

*"There are two levers to set a man in motion, fear and self-interest."*
*Napoleon Bonaparte*

*"Experience is remembering your mistakes." Oscar Wilde*

# Overview

- Definitions and historical perspective
- NELAC data integrity standards
- Benefits of ethics programs and what's involved
- Ethics areas in environmental operations
- Guidance for ethics programs
- Available ethics training and other references
- Guidelines for making ethical decisions

*"The Hallmark of Good Science: Honesty, creativity, full disclosure. There should be no scientific authorities whose views are not subject to question." Dr. Lawrence Krauss*

*"The New Normal: Honesty, integrity and authenticity." Fast Company, May 2003*

# Definitions

- Ethics: The principles of right and wrong as accepted by society or a group
- Ethical: Acceptable conduct
- Quality: Conformance to requirements
- Quality, ethical data: Data you can trust
- Data Integrity: Complete, intact information

*"The power of choosing good and evil is within the reach of all." Origen*

"*If it is not right, do not do it; if it is not true, do not say it." Marcus Aurelius*

# Why Focus on Ethics?

- EPA's Inspector General's Office has serious concerns about the ethics of environmental labs and has a very aggressive enforcement initiative aimed at identifying & prosecuting fraud
- EPA Quality Management: Falsified or fraudulent data leads to incorrect decisions and unacceptable risk to human health and the environment, as well as unnecessary expenditure of funds
- NELAC requires annual ethics/data integrity training as part of the quality systems requirement for lab certification
- ACIL recommends that laboratory owners and managers implement an effective ethics training program to ensure data integrity and to avoid serious liabilities from fraud
- Data integrity, Company integrity, Personal integrity
- SURVIVAL, SURVIVAL, SURVIVAL!

*"Everyone is entitled to their own opinion, but not their own facts."*
*Daniel Patrick Moynihan*

# Historical Perspective and Signs of Improvement

| | |
|---|---|
| 1980's | 25% of CLP labs under investigation |
| 1990's | More lab fraud and shutdowns. EPA investigates environmental labs and reformulated gasoline labs |
| 1996 | EPA Regions IX estimates that data fraud cost $11 million Published practices on detection and deterrence of fraud |
| 1999 | EPA Inspector General publishes statements on intolerance of fraud. Ethics training required in NELAC standards. IFIA implements compliance requirements for members |
| 2002 | NELAC standards require data integrity training |
| 2005 | Ethics and data integrity programs becoming a lab standard |

| | Firms w/corporate ethics programs* | Companies w/ethics codes* |
|---|---|---|
| 1980 | 7% | 13% |
| 1994 | 40% | 73% |

** The Ethics Resource Center survey*

# NELAC 2002 - Data Integrity

**Quality System Requirements**

5.4.2.6 – Data Integrity Procedures in QA Manual

5.4.2.6.1 – Data integrity training

- Signed data integrity documentation for all employees
- In-depth, periodic monitoring of data integrity
- Data integrity procedure
- Confidential reporting procedure for data integrity issues

5.4.2.6.2 – Communication to management on need for further investigation

**Personnel Training Requirements**

5.5.2.7 – Data Integrity Training

- New employee orientation and on annual basis
- Signed data integrity documentation for all employees
- In-depth, periodic monitoring of data integrity
- Data integrity procedure

*"Always do right--this will gratify some and astonish the rest." Mark Twain*

## American Council of Independent Labs
## Data Integrity Initiative Essentials

- Business Ethics and Data Integrity Policy
- Ethics and Compliance Officer
- Effective Training
- Effective Enforcement of Self-Governance Program
- Internal Investigations and Reporting of Misconduct
- Internal and External Monitoring Systems
- Data Recall Policy and Procedure

*"Living with integrity means speaking (the) truth, even though it might create conflict or tension." Barbara DeAngelis*

## Benefits of Ethics

1. Improves society and employees' work lives
2. Provides moral compass in changing times
3. Promotes teamwork and increases productivity
4. Lowers employee stress and improves health
5. Insurance policy – cheaper than litigation
6. Helps prevent criminal acts and allows reduced fines
7. Assists other mgmt. programs (quality, HR, tax, acct.)
8. Promotes strong public image
9. Improves customer trust
10. It's the right thing to do!

Plus it will help you sleep better at night.

*From Complete Guide to Ethics Management – On-line Tool Kit*

## Why are There so Many Scandals & Fraud?

- Misunderstandings about ethics – its not just about staying out of jail
- Success has been promoted over adherence to principles and values
- Pressures at work
  - 60% of workers feel more pressure than 5 years ago and 40% feel more pressure than only 1 year ago
  - 56% of workers feel some pressure to act unethically or illegally
  - 48% admitted to unethical or illegal action
    - Cutting corners on quality, covering up incidents, abusing or lying about sick days, deceiving customers, lying to a supervisor or employees, taking credits for a colleague's ideas
- Excuses for bad conduct : Everyone else does it; we've always done it that way; I'll lose my job if I don't; we'll lose client business if we don't; it's not technically significant; it won't hurt anyone

*"An ethics lapse, even for a moment, can be a career ending move." Jack Farrell*

*"I believe that ignorance is the root of all evil. And that no one knows the truth." Molly Ivens*

## What Can Be Done?

- Be a good example yourself – follow the rules
- Build a new culture of ethics that encourages, supports and allows ethical conduct
- Discuss where unethical practices start and their consequences
- Be willing to accept if something does not meet your expectations: desired results, timeliness, cost, etc. ***
- Promote full disclosure and transparency of information
- Understand that business ethics involves a combination of individual values and institutional values
- Make company/organizational values very visible

*"Once a person's mind is expanded by a new idea, the mind can never return to its original form." Oliver Wendell Holmes*

# What's Involved in Ethics Implementation?

- Rigorous honesty
- Not being able to please everyone all the time
- Willingness to change
- Awareness of the need for ethics in all areas
- Focusing on prevention of problems
- Blending personal and organization values

*Johnson &Johnson successfully handled the ethics issues in the Tylenol scare in the 1980s by having ongoing challenge sessions that clarified individual perspectives and their commitment to J&J Ethics Credo.*

# Ethics Areas in Environmental Operations

- Personal accountability
- Sample planning, collection, control and handling
- Laboratory analysis
- Data processing and management
- Report preparation, approval and distribution
- Invoices and financial reporting
- Maintaining accurate & authentic records for all of the above
- Revealing unpleasant or negative information

*"Decisions are made by individuals. Actions are taken by individuals. Companies are nothing without individual human beings, and that's where the problems start or end." Michael Deck, KPMG*

# Accuracy in Personal Accountability

- Resume
- Timesheets
- Expense reports
- Logbooks
- Computer entries
- Performance reports
- Communication and correspondence
- Follow through on your commitments to others

*"Falsehood is easy, truth so difficult." George Elliot*

*"If people are good only because they fear punishment, and hope for reward, then we are a sorry lot indeed." Albert Einstein*

# Keep Lab Staff Informed of Unethical Laboratory Behavior

- ☒ Changing the computer date/time to meet holding times or calibration windows.
- ☒ Using manual integration to inappropriately manipulate a peak.
- ☒ Spiking additional solutions to match QC requirements.
- ☒ Reporting data without actually performing the test (dry labbing).
- ☒ Using old calibration data by changing date and running with new samples.
- ☒ Knowingly omitting information from a data report or case narrative that may compromise the data.
- ☒ Performing required procedures after tests are run to meet missed requirements.
- ☒ Altering required methods to make data match, misleading client and public.
- ☒ Adding information to data after the fact without valid proof.
- ☒ Using known expired reference standards to meet a deadline.

*Reference: Jo Ann Boyd, Southwest Research Institute, "Defensibility and Ethics in the Laboratory," Quality Assurance J 2003; 7,79-83.*

## Nine Attributes of a Good Ethics Policy

1. Addressing the Big E: Ethics rather than only compliance
2. Universality – The Golden Rule and the Greatest Good
3. Sound Logical Reasoning – data driven and logical decision processes
4. Developing and sustaining ethical reasoning skills at every level Requires training, practice and rewards
5. Transforming wrong thinking, wrong actions and bad outcomes to right thinking, right action and good outcomes
6. Prevention – transform "bad" ethical rationale to "good" ethical rationale before the fact
7. Organizational change orientation
8. Employee Training – internalize, practice and support ethics principles
9. Leadership by Example – Ethics policies succeed in proportion to how much managers promote and follow them

*Reference: Dean Bottoroff, Ethics and Culture Management*

## Eight Guidelines for an Effective Ethics Program

1. Recognize that managing ethics is a process
2. The bottom line – accomplishing preferred behaviors in the workplace
3. Work toward avoiding the occurrence of ethical dilemmas
4. Make ethics decisions in groups and make those decisions public, as appropriate
5. Integrate ethics management into other management practices
6. Use cross-functional teams when developing and implementing ethics
7. Value forgiveness – recognize that effective implementation of ethics programs reveals ethical issues
8. Understand that trying to operate ethically and making a few mistakes is better than not trying at all

*Reference: Carter McNamara, Complete Guide to Ethics Management*

# Example Laboratory Ethics Related Training Courses

- EPA – Detecting Improper Laboratory Practices (www.epa.gov/quality/trcourse.html)
- Joe Solsky, U.S. Army Corps of Engineers Questionable Practices in the Laboratory
- New York Association of Approved Environmental Laboratories
- Marlene Moore, Advanced Systems, Inc. – Preventing Improper Laboratory Practices
- Yield Education and ILI – Ethics with Integrity
- Analytical Quality Associates, Inc. – Ethics and related training
- FSEA June 2005 Workshop on Identifying, Correcting and Preventing Laboratory Problems (Collaborators welcome!!)

*"Education is when you read the fine print. Experience is what you get if you don't." Pete Seeger*

*"Parents (teachers) can only give good advice or put them on the right paths, but the final forming of a person's character lies in their own hands." Anne Frank*

# Ethics Resources

- EPA Quality System (www.epa.gov/quality)
- Guidance for Environmental Data Verification and Validation (QA/G-8)
- Best Practices for the Detection and Deterrence of Laboratory Fraud
- EPA Office of Enforcement and Compliance Assurance
- EPA Region 9 QA
- EPA Region 10 QA
- U.S. Department of Defense
- ACS
- ACIL
- ASQ
- INELA
- NELAC
- Data Chem Laboratories
- University of Georgia QA Unit

*"By recognizing and abiding by high standards of conduct we do the right thing and demonstrate personal ethics." Vincent Faggioloi, US Army Corps of Engineers*

## Guidance for Making Decisions on Ethically Challenging Situations

- Use a checklist
- Obtain and consider all relevant information in order to make an appropriate, acceptable decision
- Focus on the specific question or issue
- Identify who and what is involved
- Discuss the situation with others
- Question and think before acting
- Evaluate if you can live with the outcome and consequences of your decisions

*"The ultimate measure of a man is not where he stands in moments of comfort and convenience, but where he stands at times of challenge and controversy." Dr. Martin Luther King, Jr.*

## Conclusion

By focusing on ethics in <u>all areas</u> of environmental operations,

1. The resulting work and data can be trusted,
2. Better environmental decisions can be made, and
3. The goal of protecting human health and the environment can be ensured!

*“Science may have found a cure for most evils; but it has found no remedy for the worst of them all -- the apathy of human beings.”*
*Helen Keller*

*“Try not to become a man of success, but rather try to become a man of value.”*
*Albert Einstein*

*Be cool, follow the rule.*
*American Red Cross Water Safety Instructor Training*

Ann Rosecrance

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## *Cooperative Research: "Ecological Monitoring and Assessment of the Great Rivers Ecosystem in the Central Basin of the United States" EMAP-GRE*

**Allan R. Batterman**

**Quality Assurance Manager,**

**NHEERL, Mid-Continent Ecology Division**

**24th Annual National Conference on Managing Environmental Quality Systems**

**April 11-14, 2005**

## *NHEERL, Mid-Continent Ecology Division*

Environmental Monitoring and Assessment Program for Great Rivers Ecosystems (EMAP-GRE)

EPA Technical Director: Dave Bolgrien, Research Biologist

MED Scientific Support Staff: Theodore Angradi, Research Biologist:Brian Hill, Ecologist; Terri Jicha, Physical Scientist (IM Manager); Debra Taylor, Biologist; Mark Pearson, Aquatic Biologist; Allan Batterman, Environmental Scientist (Division QAM)

## WHY "EMAP-GRE?"

Following EMAP Research Strategy (USEPA 2002)

- Use probability based designs and indicators of biological integrity to make statistically defensible and policy relevant statements about aquatic resources.
- Condition reports are the first step in the assessment; it is necessary to understand current conditions to fulfill regulatory requirements.
- States and tribes could use these methods to estimate current ecological condition of all aquatic resources.
- These methods have not previously been applied to large floodplain rivers (GRE) - Mississippi, Missouri, and Ohio Rivers.
- Sampling designs and indicators to assess large rivers are not well developed and large rivers are difficult to sample.
- These large floodplain rivers have the highest discharges and watershed areas, are critical to receiving waters, and directly impact ecological condition in marine coastal systems.

***THE MISSION - TO DEVELOP AND DEMONSTRATE THE MONITORING TOOLS NECESSARY TO ASSESS THE ECOLOGICAL CONDITION OF OUR NATION'S AQUATIC RESOURCES AND TO FULFILL THE REQUIREMENTS OF THE CLEAN WATER ACT IN A COST EFFICIENT MANNER.***

## Under MED Leadership

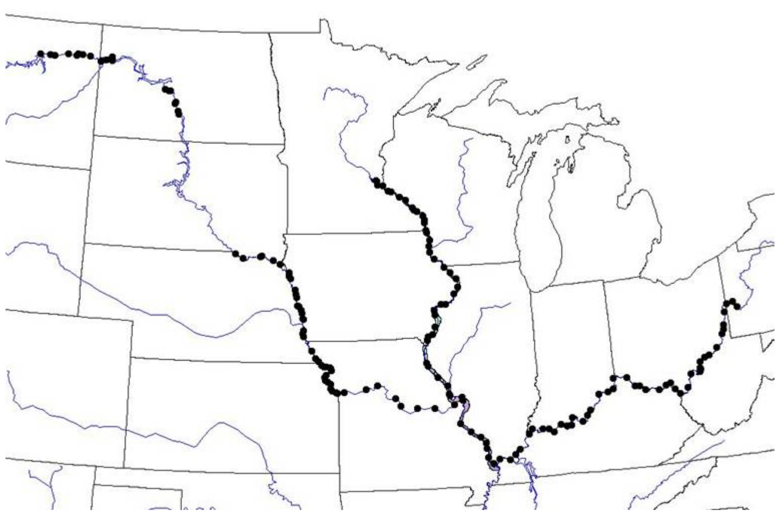
- Build on experience from Pilot Studies conducted on the Upper Missouri River, Coastal Assessment Program, and previous EMAP Projects.
- Ensure that planning is comprehensive with documentation to cover every step and in cooperation with state, federal, and interstate agencies experienced with river monitoring and assessment.
- Use Contracts, IAGs, and Cooperative Agreements as tools to develop partnerships to gather the required information on the rivers.

## *EMAP-GRE Documentation*
### *(At Start of Research)*

- EMAP-GRE Research Plan – 24 pages
- Field Operations Manual – 210 pages
  (Note: this is the working document for all field crews.)
- Quality Assurance Project Plan – 43 pages
- Field Safety Plan – 6 pages
- Animal Care and Use Plan – 10 pages
- OP Macroinvertebrate Laboratory Processing – 25 pages
- OP Sediment Toxicity Analyses – 57 pages
- PMP (USGS) Analysis of Fish Tissue Contamination – 15 pages
- OP Analyses of Sediment Enzyme Activity – 8 pages
- Grant Analysis of Periphyton and Phytoplankton for EMAP-GRE – 14 pages
- OP for Analyses of Elemental and Stable Isotopes of Total Suspended Solids and Particulate Organic Matter – 9 pages
- OP Analysis of Zooplankton – 7 pages
- Provisional EMAP-GRE Data Use Guidelines – 1 page

## Scope of the Great Rivers EMAP

**(Missouri River Reservoirs sampled under the Upper Missouri River Research Plan, which developed techniques used in this plan)**



## *What is the goal?*

To test monitoring methods that are more economical while maintaining scientific validity.

The ultimate measure of program success will be to have the approaches adopted by state and federal managers who conduct routine monitoring and assessment.

## Great Rivers EMAP Organization

MED has Overall Leadership at all stages

**EPA ORD NHEERL Director**
**Associate Director for Ecology**
**EMAP Director**

**MED (Duluth) Division Director**

**Technical Lead**

**Management Team**

| Project Administration | Quality Assurance |
|---|---|
| Health & Safety | Extramural Funding |

**Science Teams**

| Sample Design | Methods/ Training |
|---|---|
| Information Management | Data Analysis / Assessment |

**Partners**

| Upper Missouri River | Lower Missouri River | Upper Mississippi River | Ohio River | Analyses |
|---|---|---|---|---|
| -EPA Region 8<br>-Fort Peck Tribe<br>-USGS in ND & Montana<br>-ND Dept Health | -EPA Region 7<br>-USGS in Missouri, Iowa, Kansas, Nebraska<br>-Missouri Dept of Conservation<br>-Nebraska Game & Fish Commission<br>-University of Iowa | -EPA Region 5<br>-USGS Upper Midwest Environmental Sciences Center<br>-Wisconsin DNR<br>-Minnesota DNR<br>-Iowa DNR<br>-Illinois Natural History Survey<br>-Missouri Dept of Conservation | -EPA NERL<br>-EPA Region 3<br>-EPA Region 5<br>-ORSANCO<br>-SoBran Inc | -University of Louisville<br>-Stroud Water Center,<br>SW Missouri State University<br>-USGS UMESC<br>-EPA NERL,SoBran Inc.<br>-EPA NHEERL, Wilson Env. Labs |

## *Cooperator Breakdown*

Inter Agency Agreements (IAG)

- Field Crews
  - USGS - 4
  - State under USGS Funding – 6+ **(some assistance to USGS Crews via IAG Funding)**
- Analytical Laboratories – 6 (federal, state, and private)

Contracts - 2

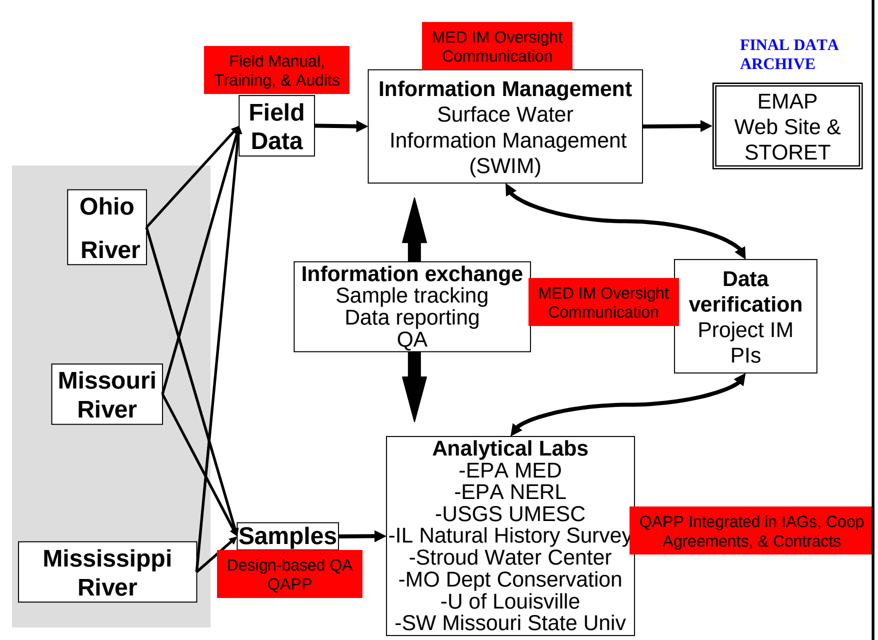
- NERL – SoBran, Inc.- Field and Analytical Support
- NHEERL, MED – Wilson Environmental Lab - Tax.

Grants

- River Monitoring – direct to GRE states (17 potential)
- Periphyton Analysis – (RFP)1

18 different organizations are participating in this Research Plan.

## Laboratory and Information Management QA Basics



## *Headlines from the EMAP-GRE Program*

**PLANNING DOCUMENTS**
- Approved Research Plan and QAPP
- Collaborations result in 225 page Field Operations Manual (FOM)
- Multiple Analytical Labs Submit OPs
- EMAP-GRE Newsletter produced starting in March 2005 to highlight program activity and challenges

**TRAINING, PLANNING, AND DEBRIEFING**
- Four 3-day sessions train 85 people from 9 agencies
- Post-season debriefing teleconference sessions conducted
- Post -season Technical Meeting to discuss all points necessary for completion of the research

**INTERNAL MEETINGS**
- On-going weekly Principal Leaders Meetings held to discuss program activity and events

**INFORMATION MANAGEMENT**
- All-hands emails keep crews informed, provide FOM corrections/alerts
- Web-based Sample Tracking System implemented -
  - Surface Water Information Management Systems (SWIMS) used by other EMAP projects
  - Provisional EMAP-GRE Data Use Guidelines

**FIELD AUDITS**
- Field Audits completed for all crews
- Audit revealed -
  - Wrong bank sampled, crew re-sampling site. Site layout rules reviewed.
  - Duplicate Sample IDs found in database, obsolete labels identified and removed.
  - Inadequate Fish Vouchers collected, crews to increase photo or specimen vouchers.
  - Confusion over landcover classes, glossary added to Manual.
- Lab Audits to be completed

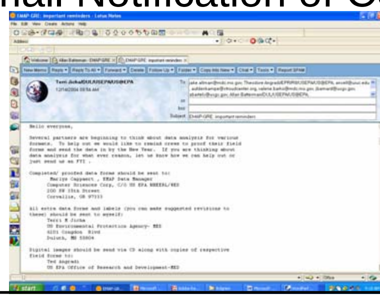
## *The EMAP-GRE Program*

| *Design-based QA Requirements* | *Field Operations Manual* | *Information Management* | *Communication* | *Field Training* | *Field Audits* |
|---|---|---|---|---|---|
| 20% site re-visits by river<br><br>10% duplicate and blank samples by crew | Single authoritative source.<br><br>Used in training<br><br>Written with partners<br><br>Updates tracked<br><br>Contains all standard forms and labels | Single source of forms and labels<br><br>Tracks samples<br><br>Accessible to crews and labs | "All-hands" email alerts to crews<br><br>Logs decisions made and corrective actions<br><br>End-of-season debriefing<br><br>Conference calls<br><br>Technical Committee Meetings<br><br>Newsletter | Hands-on and realistic<br><br>Include all procedures and forms<br><br>Time for practice<br><br>Review of site dossiers | Face-to-face visit with each crew while sampling<br><br>Crew-specific corrective actions<br><br>As needed, all-hands emails |

## *Communications*

Newsletter – e-mail distribution

E-mail Notification of Concerns –



## *What is the current focus?*

- Program Objectives
- Field Data Collection (2004-2005)
- General Strategy
- SWIMS Data Base fields – 2004 Field Data Verification On-going
- Are we gathering information so that it can be easily searched and cross referenced ?
- Was training adequate ?
- Lessons learned ?
- From results obtained in the first season, does the Field Operations Manual need to be modified ?

## *Further Information ?*

How do I get on the e-mail list for the Newsletter ? Contact Pearson.mark@epa.gov

How do I get a copy of the Field Operations Manual or any other planning document?

Contact Batterman.allan@epa.gov

Any Questions ?

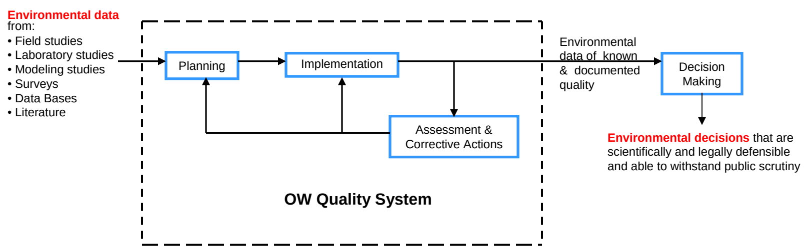
## Process for Developing and Approving Quality Assurance Project Plans (QAPPs)

D. King Boynton
boynton.king@epa.gov
Office of Wastewater Management
Environmental Protection Agency

24th Annual National Conference on Managing Environmental Quality Systems
April 11- 14
San Diego, California

## OW Quality System

- Set of rules and requirements
- System with components (processes)
  - < Planning processes
  - < Implementation processes
  - < Assessment processes




The Quality System's Role in Decision Making

## Process for Developing and Approving QA Project Plans (QAPPs)

Go to page 2 of the paper to view a readable copy of this slide.

## Process for Developing and Approving QAPPs

1. Review Work Assignment & complete Environmental Data Review (EDR) Form

Purposes of the EDR Form (See page 6 of paper)

- C To educate the Work Assignment Managers (WAMs)
- C To provide the EPA definition of “environmental data”
- C To identify which tasks involve environmental data
- C To identify the types of data
- C To identify how the data will be used

## Process for Developing and Approving QAPPs

2. Determine which tasks need QA requirements & prepare the Work Assignment’s QA task

Purposes of Work Assignment’s QA task:

- C To identify which tasks should be supported by a QAPP
- C To provide the contractor with instructions on developing the QAPP and QA reporting

## Process for Developing and Approving QAPPs

### 3. Complete the Contracts QA Review Form

- This form provides information for Contracting Officers

### 4. Review and approve the Work Assignment

- Once the Work Assignment is approved, the contractor may start working on any tasks not needing a QAPP

## Process for Developing and Approving QAPPs

### 5. Prepare the QAPP to:

- Describe appropriate data quality requirements for the tasks identified as needing a QAPP
- Describe methods and procedures for meeting these requirements

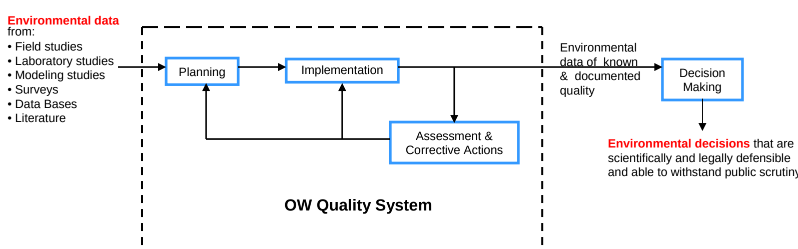
### 6. Review and approve the QAPP

- Start work on all tasks
- Incremental, task-by-task, development and approval of the QAPP to expedite starting work on the high priority tasks

# Process for Developing and Approving QAPPs

- For the process to be effective, it must also be an educational process because most WAMs have not read the Quality System guidance or their Program Office QMP

- Educational materials
  - < The Quality System's Role in Decision Making (slide)
  - < Process narrative description & flow chart (handout)
  - < Environmental Data Review (EDR) Form




The Quality System's Role in Decision Making

## Caveat

- This work is evolving to meet our needs. Although it is beginning to be used, it should be considered a draft because it has not yet been formally approved.

# DETERMINING THE COMPETENCE OF AUDITORS

Gary L. Johnson

U.S. EPA

QUALITY STAFF

RESEARCH TRIANGLE PARK, NC

## Objectives of This Workshop

- Discuss the concept of competence.
- Describe the principal elements of competence.
- Discuss personal attributes.
- Discuss knowledge and skills.
- Describe selection and evaluation of auditors.
- Describe role of continual professional development.

## Concept of Competence

## Competence

- Auditors are made, not born.
- Audit program success depends on:
  - Implementing the audit process effectively, and
  - Competence of the auditors.

## Elements of Competence

## Elements of Competence

- Personal attributes.
- General knowledge and skills related to auditing principles and practices.
- Specific knowledge and skills that apply to QMS or EMS auditing.
- Appropriate levels of education, work experience, auditor training, and audit experience.

## Personal Attributes Needed

- Demonstrated Personal Attributes include:
  - Ethical
  - Open minded
  - Diplomatic
  - Observant
  - Perceptive
  - Versatile
  - Tenacious
  - Self-reliant
  - Decisive

## Personal Attributes

- Other considerations:
  - Able to work as part of a team, and
  - Willingness to be an auditor.
- Not all attributes may be needed for a particular audit program.

## Audit Principles and Practices

## Audit Principles and Practices

- An auditor should have the general knowledge and skills to:
  - Apply audit principles, procedures, and techniques.
  - Plan and organize work effectively.
  - Conduct the audit within schedule.
  - Prioritize and focus on significant issues.
  - Collect information through effective interviewing and document reviews.
  - Understand use of sampling techniques for auditing.

## Audit Principles and Practices contd.

- An auditor should have the general knowledge and skills to:
  - Verify the accuracy of collected information.
  - Determine the reliability of the audit evidence.
  - Be able to develop and sustain audit findings.
  - Use work documents (i.e., checklists) to record data.
  - Prepare audit reports.
  - Maintain the security and confidentiality of information.
  - Communicate effectively, both verbally and in writing.

## Audit Team Leaders

## Audit Team Leaders

- Audit team leaders should meet the requirements to be an auditor and:
  - Demonstrate supervisory and leadership skills.
  - Have the needed communications skills to perform as an audit team leader.
  - Be able to prevent and resolve conflicts.
  - Provide direction and guidance to auditors-in-training.
  - Represent the audit team in communications with the auditee.

## QMS and EMS Audits - Knowledge and Skills

## QMS and EMS Audits – Knowledge and Skills

- Auditors should understand the management system, including:
  - Application to the organization and its programs.
  - Interaction among components of the management system.
  - Relevant standards and policies used as audit criteria.
- Auditors should understand relevant documents, manuals, etc., for the management system.

## QMS and EMS Audits – Knowledge and Skills

- An auditor should understand:
  - Organizational size, structure, functions.
  - General business processes (i.e., what they do).
  - Cultural aspects of the organization.
- An auditor should have at least a working knowledge of:
  - Applicable laws and regulations.
  - Contracts and other agreements.

## Education, Work Experience, Auditor Training, and Audit Experience

## Education, Work Experience, Auditor Training, and Audit Experience

- **The minimum levels should be determined by the organization and defined in the audit program.**
- **Each will vary according to the needs of the audit program.**

## Education, Work Experience, Auditor Training, and Audit Experience

- **Education:**
  - **An auditor should have completed an education sufficient to acquire the knowledge and skills needed.**
- **Work Experience:**
  - **Demonstrate work experience related to the field (e.g., quality management, environmental management).**

## Education, Work Experience, Auditor Training, and Audit Experience

- **Auditor Training:**
  - **An auditor should have completed auditor training sufficient to acquire the knowledge and skills needed.**
- **Audit Experience:**
  - **Demonstrate audit experience in planning and conducting audits under the direction of a competent Audit Team Leader.**

## Selection of Auditors

## Selection of Auditors

- **Systematic selection program is needed and should be based on:**
  - **Specific needs of particular audit program.**
- **Selection process should include:**
  - **Identification of potential auditors.**
  - **Initial evaluation and specific training.**
  - **Identification of potential audit team leaders.**
  - **Match knowledge and skills to audit scope and criteria.**

## Auditor Evaluation

## Auditor Evaluation

- **An auditor evaluation program is needed to:**
  - **Initially evaluate persons who wish to become auditors,**
  - **Consider auditors for selection for a particular audit team, and**
  - **Provide for the on-going evaluation of auditor performance.**

## Auditor Evaluation Process

- Apply a systematic evaluation process that:
  - Identifies the needed personal attributes and knowledge and skills for the audit program.
  - Set specific evaluation criteria.
  - Select an appropriate evaluation method.
    - Observation
    - Testing
    - Records review
    - Interviews
  - Conduct the Evaluation.

## Maintenance and Improvement

- Maintenance and improvements may be accomplished through:
  - Continuing professional development:
    - Additional training in audit techniques
    - Participation in mentoring programs
    - Self-study programs
  - Participation in additional audit programs.

## Summary

- Auditor competence is a key factor in QMS and EMS audit success.
- Auditor competence is defined by demonstrated personal attributes and knowledge and skills gained through:
  - Education
  - Work experience
  - Auditor training
  - Audit experience

## Summary contd.

- Auditing is like any profession:
  - Auditing must be learned.
  - Auditing must be maintained.
- Auditors are made, not born.

## Summary contd.

This workshop is based on guidelines found in ANSI/ISO/ASQ QE 19011S-2004, the U.S. Supplement to ISO 19011:2002.

## LAST WORD

- Thank you and good day.

# A Bayesian approach to detection limits in analytical chemistry

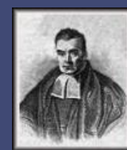
Bradley Venner
USEPA
venner.brad@epa.gov

## Disclaimer

- *I am a member of the internal EPA workgroup for the OW FACA process; therefore*
  - I will focus only on technical statistical issues related to detection limits
  - Regulatory issues not be discussed
  - I will not discuss EPA's MDL procedure
  - All opinions are mine and do not reflect Agency thinking

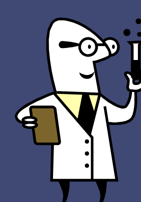
# What are the potential advantages of a Bayesian approach to detection limits?

1. Can justify calculation of both performance characteristic limits and censoring value
2. Consistent framework to handle parameter uncertainty
3. Use of Bayesian decision theory to extend hypothesis testing framework



# What are detection limits?

- Detection Decision: An analyte is “present” in a sample
- Detection Criteria: Criteria placed on signals and/or observations to make a detection decision
- Detection limit: The smallest amount of an analyte that will be “reliably detected”



## Two Types of Detection Decision Criteria

- Primary (Instrumental) Detection Criteria
  - Detection decision is based on requirements for qualitative identification
  - Criteria can be quite complex in contemporary instruments (GC-MS, NMR, etc)
- Secondary (Method) Detection Limits
  - Detection decision is based on comparison to a population of “blanks”
  - Necessarily application dependent due to need to define appropriate “blanks”

## How Are Detection Limits Used?

- Method Performance Characteristic
  - Choose between analytical methods
- Reporting of Analytical Results
  - Regulatory reporting limits
  - Censoring levels
    - Reported if a non-detect is obtained during application of a method

# IUPAC's Recommended Approach to Detection Limits

- Critical value
  - The critical value $L_c$ is a detection decision criteria such that

$$P(\hat{L} > L_c \mid L = 0) \le \alpha$$

- Detection limit
  - Minimum detectable value; that value for which the false negative rate is β, given $L_c$

$$P(\hat{L} \le L_C \mid L = L_D) = \beta$$

# What are some limitations with IUPAC approach?

- Focus on Type 1 Error
- Extension to complex primary detection criteria and multicomponent detection
- Restriction to use as a performance characteristic (sort-of)
- Handling uncertainty due to empirical estimation of detection limits (sort-of)
- Application to more complex decisions

# Complex Primary Detection Criteria Are Not Set Using Statistical Techniques

- Need to distinguish between “critical value” and “detection decision criteria”
  – Primary detection decision criteria can be quite complex in contemporary instruments
  – Primary detection decision criteria are not usually set statistically; Type 1 error rate is often unknown due to signal censoring

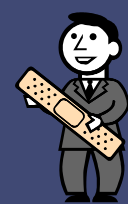
- Performance of criteria can still be investigated statistically

# Is calculating the critical value first absolutely necessary?

- Given a primary detection decision criteria
  – Run replicates of known concentrations
  – Observe detection results
  – Lower spike concentration until non-detects are observed
  – Detection limit is above the concentration where non-detects are observed
- Avoids the need for mathematcial modeling at low analyte levels
- Controls false negative rate

## Restriction to use as a performance characteristic

- Evaluation model is obtained by inversion of calibration model using Bayes' law
- Detection limits are obtained with the calibration model
  - Hypothesis testing framework (Clayton, 1987)
- Censoring values are obtained with the evaluation model
  - Estimation problem (Brown, 1996)



## Empirical Estimation of Detection Limits

- Detection limits are estimated from empirical data and thus are uncertain
- Bayesian approach allows for consistent handling of parameter uncertainty
- Contemporary methods of calculation for Bayesian models can be used

## Applications to more complex decisions

- The use of detection limits in the regulatory domain is more complex than the analytical domain
- Need to weigh benefits versus costs of detection decisions
- Bayesian decision theory (Bayesian probability + utility theory) can be applied to make more informed tradeoffs
- Value of information approaches to design of procedures to estimate detection limits
- Status:  vaporware

## What is the Bayesian approach to analytical chemistry?

- Specification of probabilistic calibration model
- Estimation of parameters in probabilistic calibration model using data obtained from a calibration design
- Inversion of probabilistic calibration model to obtain probabilistic evaluation model

## Estimation of Parameters in Calibration Model

- Calibration Design: Obtain instrumental responses $R_i$ for n standards at analyte concentrations $C_i$

$$\mathrm{L}(\mathrm{R} \mid \theta, \mathrm{C}) = \prod_i \mathrm{P}(\mathrm{R}_\mathrm{i} \mid \theta, C = C_i)$$

$$P(\theta \mid \mathrm{R}, \mathrm{C}) = \frac{\mathrm{L}(\mathrm{R} \mid \theta, \mathrm{C})\, P(\theta)}{\int \mathrm{L}(\mathrm{R} \mid \theta, \mathrm{C})\, P(\theta)\, d\theta}$$

## Inversion of Calibration Model to Obtain Evaluation Model

- Measure j replicates of unknown
- Uniform prior probability for analyte concentration from zero to 1.5 times the upper instrumental range
- Invert calibration model using Bayes' Law

$$\mathrm{P}(\mathrm{C} \mid \mathrm{R}_\mathrm{u}, \theta) = \frac{P(R_u \mid \theta, C) P_u(C)}{\int P(R_u \mid \theta, C) P_u(C) dC}$$

## Conditional and Marginal Models

- Both calibration and evaluation models were expressed as conditional on model parameters
- Uncertainty in parameters can be accounted for by integrating model over the parameter distribution
- Known as “marginal” model (using Bayesian parlance)

## Example: Single Signal, Single Analyte, Constant Variance

- Most common situation treated in literature; good basis for comparison with other approaches
- Analytical solutions can be found
- Can be considered either a primary or secondary detection decision criteria

# Calibration model

- Conditional model
  - R=mC + B + σ
- Marginal model
  - Jeffries' prior distribution P(m,B,σ)= 1/ σ
  - Posterior parameter distribution
    - m,B have t-distribution
    - σ has an inverse-chi-square distribution

# Evaluation Model

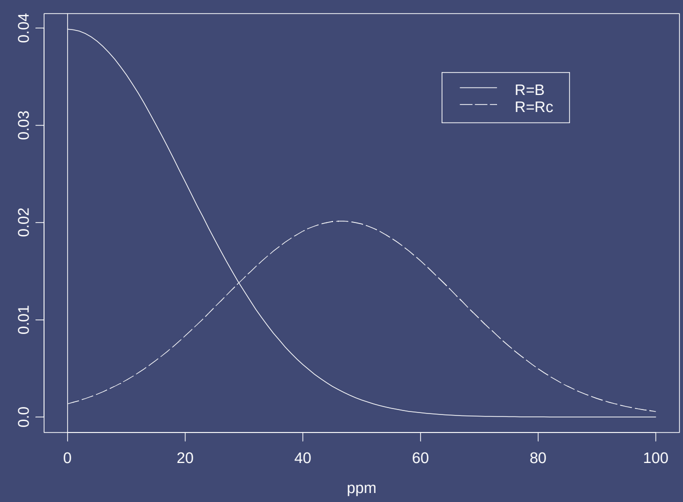
- For uniform prior distribution over (0,1)

$$P(C \mid R_u, \theta) = \begin{cases} if\ 1 \geq C \geq 0 & \dfrac{1}{K\sigma\sqrt{2\pi}} \exp\left[ \dfrac{-\left(C - \left(\dfrac{R_u}{m} - \dfrac{B}{m}\right)\right)^2}{\dfrac{2\sigma^2}{m^2}} \right] \\ otherwise & 0 \end{cases}$$

$$K = [\Phi((\mathrm{B} + \mathrm{m} - \mathrm{R_u})/\sigma) - \Phi((\mathrm{B} - \mathrm{R_u})/\sigma)]$$

- Truncated normal distribution
  - Probability mass at C=0 equals false positive rate at $R_u$

## Example conditional evaluation model; σ/m = 20 ppm




## Critical value and detection limit with conditional calibration model

- Critical value (conditional model)
  - Find response level $R_c$ such that $P(R>R_c|\theta,C=C_0)<\alpha$
  - $R_c=\sigma\Phi(1-\alpha)\ + B$
- Detection limit (conditional model)
  - Find smallest concentration $C_d$ such that $P(R<R_c|\theta,C=C_d)<\beta$
  - $C_d = [\Phi(1-\alpha)+ \Phi(1- \beta)]\ \sigma /m$
- Same as IUPAC; uncontroversial

## Critical value and detection limit with marginal calibration model

- Rather than a single operating characteristic curve, there is a family of curves
- Complicated by need to consider calibration design
- With vague prior distributions for parameters, results are identical to those in Clayton, Anal. Chem., 59:2506-2514 (1987)

## Censoring limit; conditional evaulation model

- Find upper bound on analyte concentration given response $R_u$
- If $R_u = R_c$, then upper 1-β posterior density quantile is the (conditional) DL
- Justifies use of the DL as a censoring value (i.e. as a maximum value)

## Censoring limit; marginal evaulation model

- Exercise left to the reader

## Conclusions

- Detection limits are relative to:
  - Calibration model and design
  - Detection decision criteria
  - Number of replicates of unknown
- Bayesian approach supports the use of the DL as a censoring value

## Future Work

- Extension to more interesting applications
  - Multi-variate calibration
  - Non-normal instrumental response
- Applications of decision analysis

## References


- Defining the smallest analyte concentration an immunoassay can measure. Brown EN, McDermott TJ, Bloch KJ, McCollom AD. Clin Chem 1996; 42:893-903
- Nomenclature in Evaluation of Analytical Methods Including Detection and Quantification Quantities. IUPAC, Analytical Chemistry Division. Pure & Appl. Chem 1995; 67:1699-1723
- Detection Limits with Specified Assurance Probabilities. Clayton, CA, Hines JW, Elkins, PD. Anal. Chem 1987; 59:2506-2514

Thank You!

# The Problem of Statistical Analysis With Nondetects

Dennis Helsel

U.S. Geological Survey

## Statistical term: “censored data”

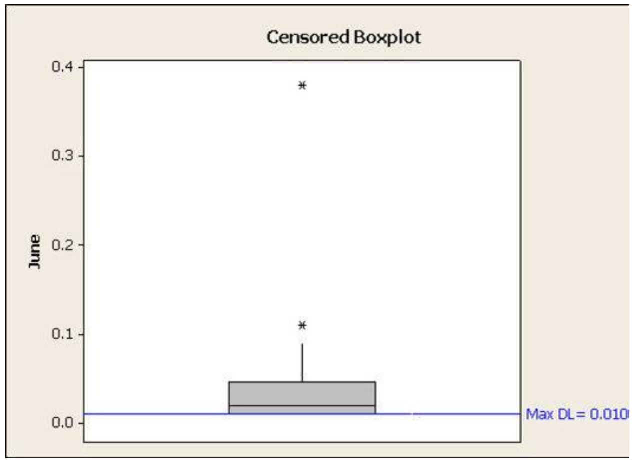
- Data known only to be above or below a threshold. The exact, single number is not known.
- In environmental studies, most frequent application is to “nondetects”, values known only to be below reporting (detection) limits.

# Primary application:
## Left-Censored Data

"Nondetects" or "less-thans"

Concentrations reported as below a laboratory threshold:

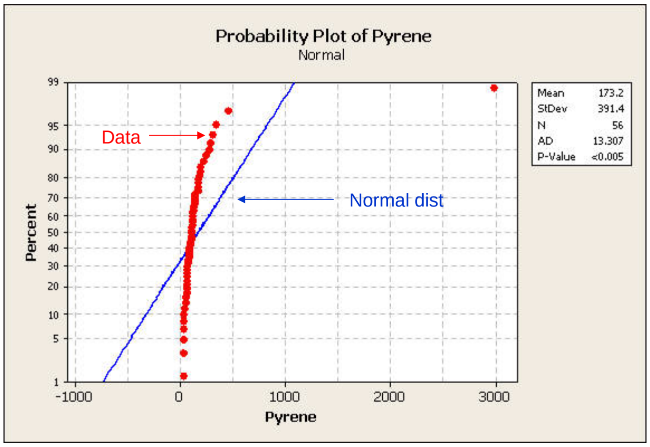
"<0.01"




# Definition: "reporting level"

- Laboratory reporting threshold. Above this threshold a single number is reported. Below is reported a nondetect ("less-than") or a qualified ("caution: low precision") value.
- Are several types of reporting levels.
  - Detection limits
  - Quantitation limits
- I won't differentiate today. Just RL.

# Definition: “probability plot”



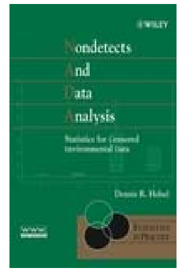

A plot of the percentiles of data. Normal distribution looks like a straight line. Nonlinear % (y) scale.

# “Nondetects” occur in many fields

- Water quality
- Air quality
- Soil chemistry
- Geochemistry
- Astronomy
- Occupational health
- Risk analysis
- Biocontaminants

More detail is available in the new book:

# **N**ondetects **A**nd **D**ata **A**nalysis



**Statistics for Censored Environmental Data**

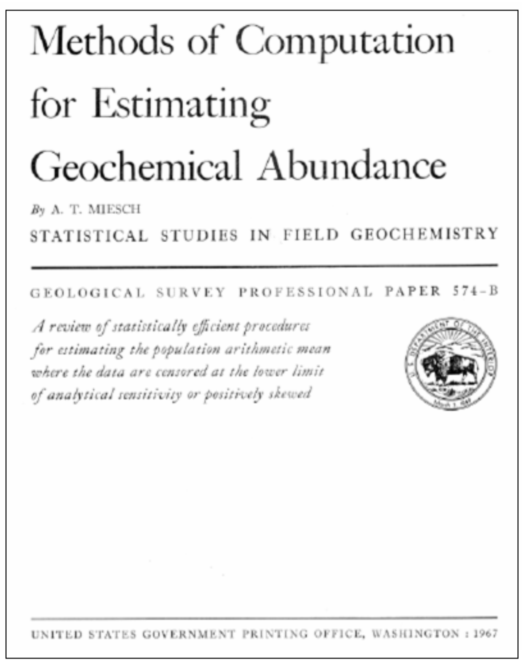
**by Dennis R. Helsel**

**Wiley (2005)**

**Web site: PractivalStats.com / nada**

Miesch (1967) first report I have found that applied an 'advanced' method

Recommended Cohen's MLE to compute mean of censored geochemical data



Methods of Computation for Estimating Geochemical Abundance

*By* A. T. MIESCH

STATISTICAL STUDIES IN FIELD GEOCHEMISTRY

GEOLOGICAL SURVEY PROFESSIONAL PAPER 574-B

*A review of statistically efficient procedures for estimating the population arithmetic mean where the data are censored at the lower limit of analytical sensitivity or positively skewed*

UNITED STATES GOVERNMENT PRINTING OFFICE, WASHINGTON : 1967

## The Problem

- 38 years after Miesch, substitution is still the most commonly-used method for incorporating censored environmental data
- $\frac{1}{2}$ or $\frac{1}{\sqrt{2}}$ times RL are the most commonly-used substitutions
- Using ½, each <1 becomes 0.5, each <5 becomes 2.5, etc.

## What's wrong with substitution?

- Is this a good method?
- If not, why not?
- A typical example

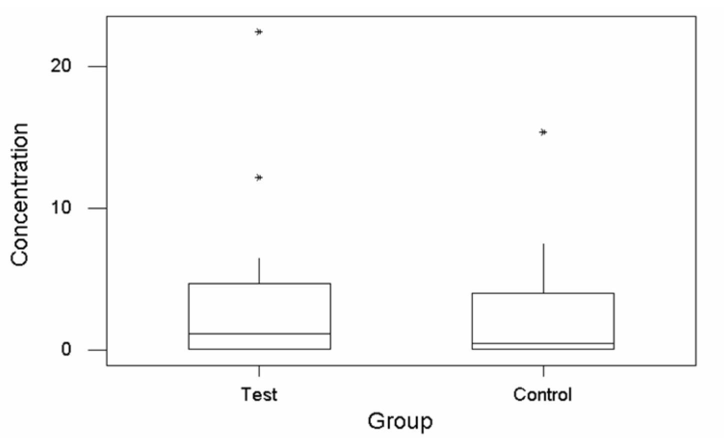
## Example 1

Control group versus Test group

(background versus possibly elevated)

- Metals in soils
- Lead in blood of children
- Pesticide residues in birds
- Test to see if the 2 groups are same or different

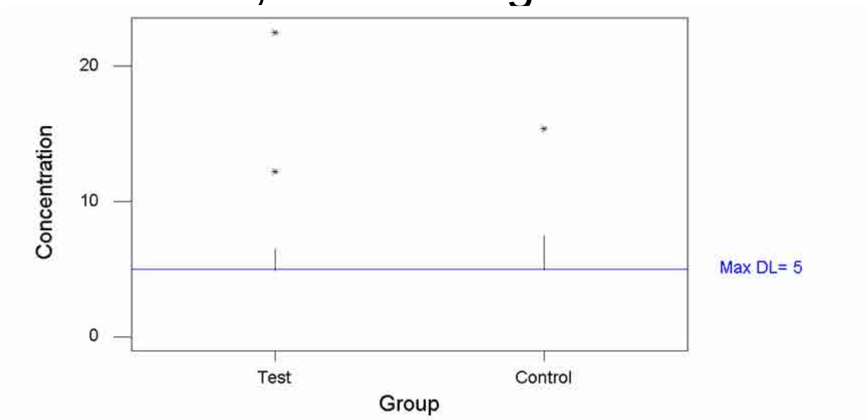
## Original data. No difference




Before censoring: Mann-Whitney rank-sum test

p-value = 0.43

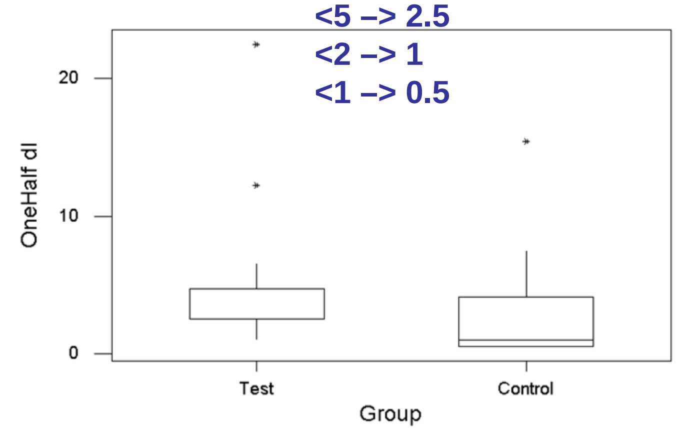
## Set reporting levels at 1, 2 and 5 ug/L




80% of data below 5 ug/L in both groups

More rl=5 assigned to Test than Control group

## Substitute 1/2 rl for nondetects




Mann-Whitney p-value = 0.015

Incorrectly state that Test > Control group.

**$$$$**

# Problems with substitution (fabrication) of data

1. Assumes we know more than we do
2. Multiple reporting levels can generate false signal

   Numbers substituted represent lab conditions, not what was in the sample
3. Can get different test results depending on the (arbitrary) constant substituted
4. Result: can change true no difference to a difference, and vice-versa

# Unfortunately, substitution is still being recommended:

United States Environmental Protection Agency | Office of Research and Development Washington, D.C. 20460 | EPA/600/R-96/084 January 1998

**GUIDANCE FOR DATA QUALITY ASSESSMENT**

Practical Methods for Data Analysis

**EPA QA/G-9**

**QA97 Version**

Recommended Methods:

- Substitute 1/2 RL if <15% nondetects (15% is enough to change a regression)
- Between 15-50% nondetects use Cohen's method (is only for 1 RL)
- Above 50%, use contingency tables (collapses all detected data to one value)

## Some of the EPA guidance documents for interpreting censored data

- Technical Support Doc for Water Quality Based Toxics Control
- CERCLA guidance
- Addendum to Interim Final Guidance for RCRA sites
- Aquaculture Technical Development Document
- Guidance for Data Quality Assessment: Practical Methods for Data Analysis

## Most-often recommended methods for computing descriptive statistics in USEPA guidance documents

- Substitute 1/2 RL
- Cohen's MLE (1959)
  - only for 1 RL
- The Delta-Lognormal method (1955)
  - is really just substitution

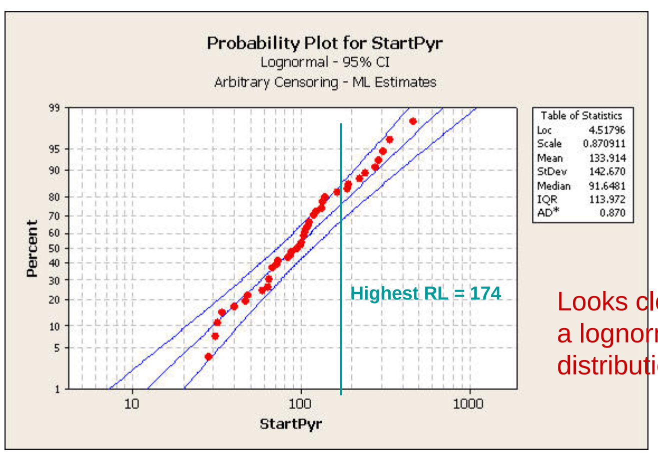
**Hasn't the state of the science advanced since 1959 ?**

## Some problems with current methods for nondetects when

1. Estimating descriptive statistics
2. Running hypothesis tests
3. Plotting data
4. Computing a regression equation

## Example censored data set

- Pyrene concentrations in benthic sediments. 56 observations, 11 censored at 8 RLs. From She (Journal of the AWRA, 1997)




Looks close to a lognormal distribution

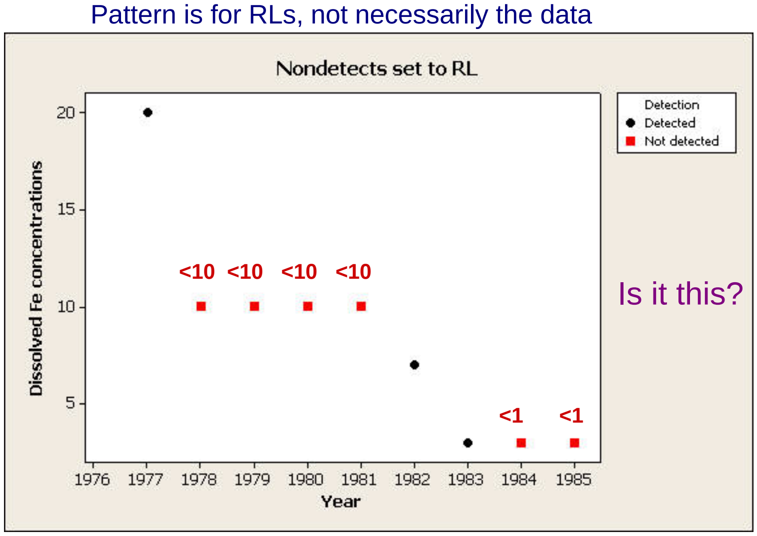
# Substitution is arbitrary

## Calculated Descriptive Statistics

| Substitution Method | N | Mean | StDev | Median |
|---|---|---|---|---|
| Nondetect = RL | 56 | 173.2 | 391.4 | 104.0 |
| Nondetect = 0 | 56 | 152.8 | 396.5 | 86.5 |
| difference | | 13% | | 21% |

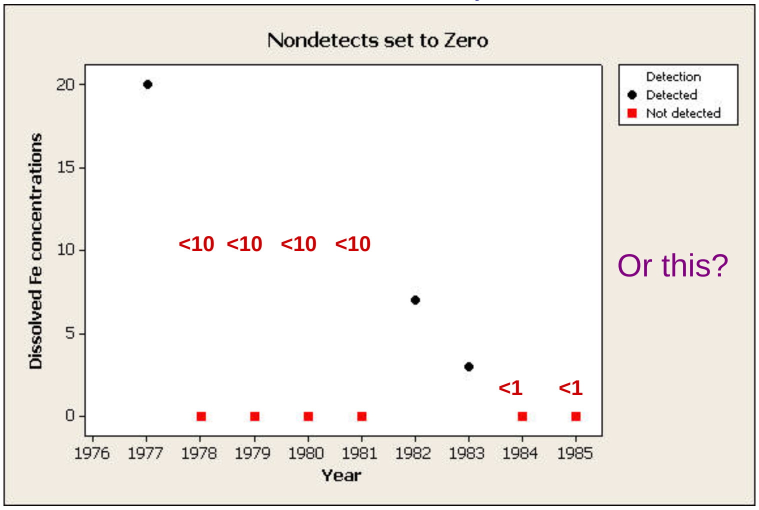
# Scatter plots

Nondetects shown at arbitrary values
Pattern is for RLs, not necessarily the data



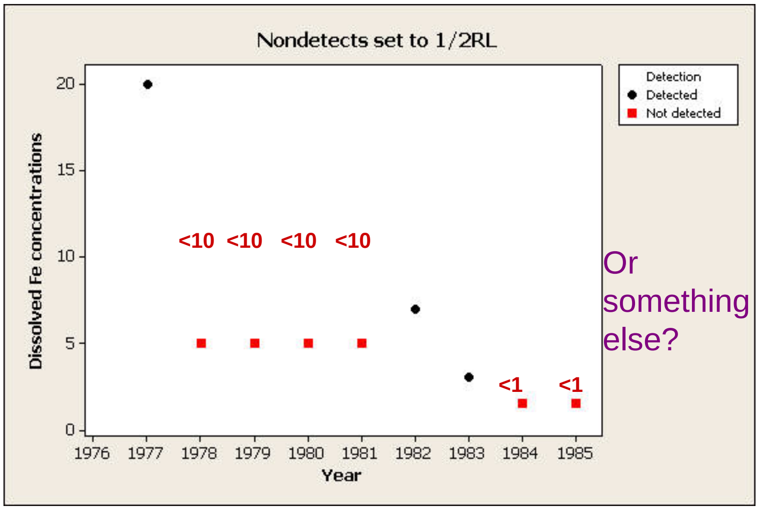
# Scatter plots

Nondetects shown at arbitrary values
Pattern is for RLs, not necessarily the data




# Scatter plots

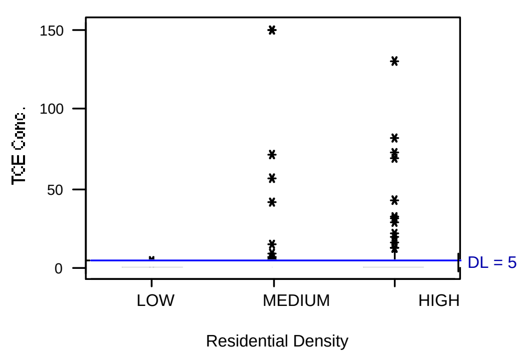
Nondetects shown at arbitrary values
Pattern is for RLs, not necessarily the data



## Hypothesis Tests for Censored Data

1. Substitution doesn't work well
   (Example follows)
2. Never delete less-thans !

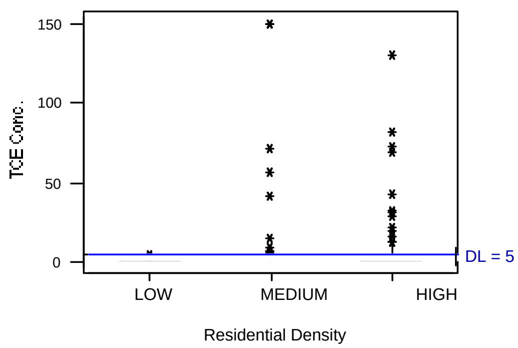
## TCE concentrations in GW




Data censored at 5 ug/L

Does TCE distribution differ among the three land-use groups?

## Substitution




**p-value**

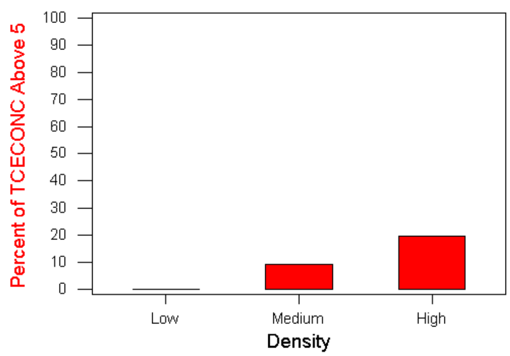
**ANOVA <5 = 0 0.57**

**ANOVA <5 = 5 0.50**

**Kruskal-Wallis 0.01**

## Simplest nonparametric test: Contingency Tables

Is % of TCE concentrations above 5 ug/L different?




Yes.
p = 0.003

No substitution required

% above: 0 9 20

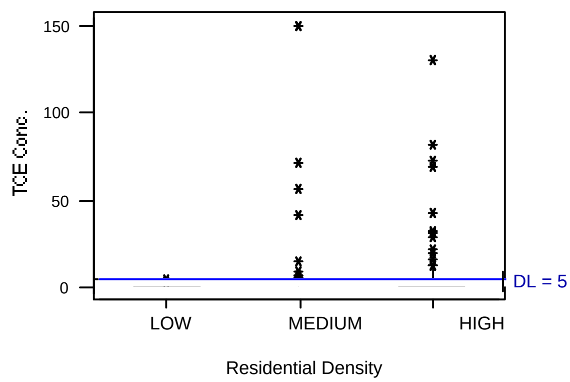
## For one detection limit

- Can always run a nonparametric test
- All nondetects are tied at lowest rank
- Proportion of ties captures low-end information
- No fabrication
- Results are unequivocal

## Testing groups with multiple RLs

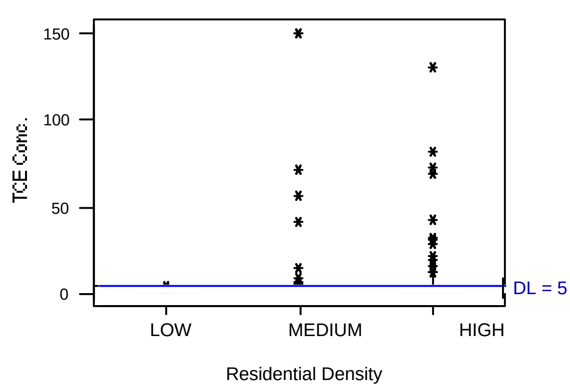
- Biggest issue: substituting values that are a function of the RL may introduce a false signal. May also do the reverse.

## Multiply-censored data



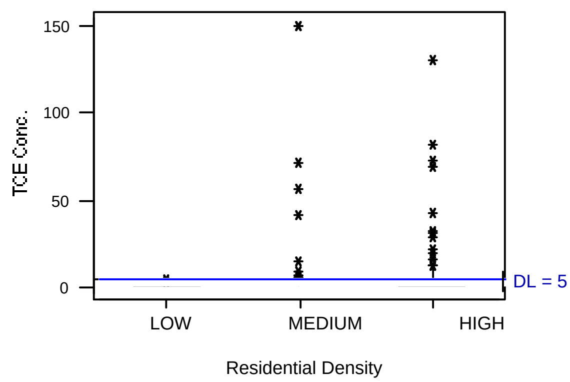

- TCE concentrations actually censored at 1, 2 and 5 ug/L

## Multiply-censored data




Need a way to incorporate <5s, <2s, <1s and 2s 3s and 4s into a valid test procedure

# Multiply-censored data

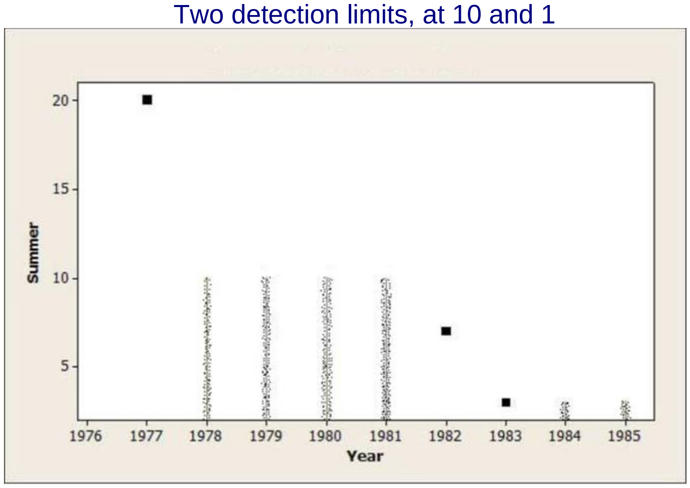



There are better ways

See next talk!

## Is there a correlation between Y and X (time)?

Is there a trend?
Two detection limits, at 10 and 1



## Correlation and regression with substitution. Results disagree.

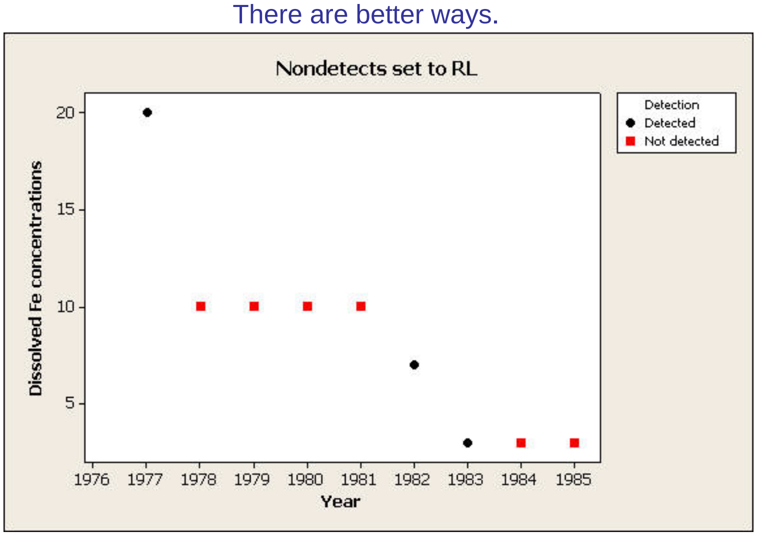
| Summer conc | Pearson's r | Slope | p-value |
|---|---|---|---|
| DL | -0.80 | -1.77 | 0.001 |
| 1/2 DL | -0.71 | -1.44 | 0.034 |
| zero | -0.46 | -1.12 | 0.216 |

Which is correct? Two substituted values produce a trend ($p < 0.05$). A third does not.

## Induced trend?

Substitution will turn changing reporting limits into a trend in Y, when Y may not have been changing.

There are better ways.



## Summary

Problems with common procedures for interpreting data with nondetects

1. Answers change with arbitrary decisions
2. Signals imputed that may not be in the original data
3. Says that we know more than we do
4. There are excellent alternatives!

# Survival Analysis Methods for Interpreting Data With Nondetects

Dennis Helsel

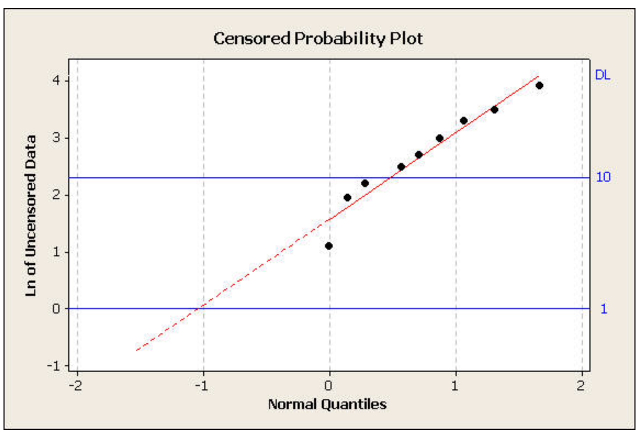
U.S. Geological Survey

## The information is in the proportions below each level

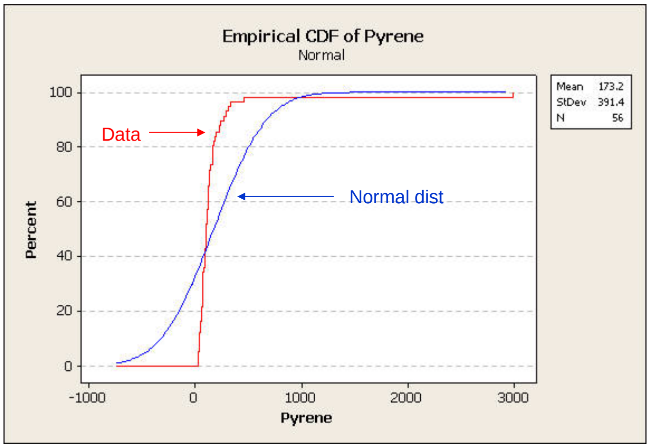
The proportion of nondetect values is known.

This proportion, plus detected concentrations, are used in data analysis.

Quantiles (percentiles) for detected values adjusted for proportion of nondetects

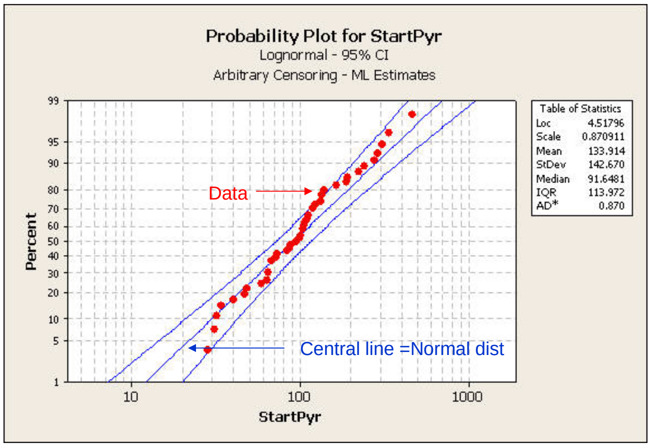


# Definition: “cdf”




A plot of the percentiles of data. Normal distribution looks like an “S” curve. Linear % (y) scale.

# Definition: “probability plot”

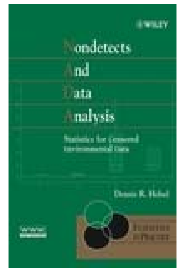



A plot of the percentiles of data. Normal distribution looks like a straight line. Nonlinear % (y) scale.

More detail is available in the new book:

**Nondetects**
**And**
**Data**
**Analysis**

**Statistics for Censored Environmental Data**



**by Dennis R. Helsel**

**Wiley (2005)**

www.PracticalStats.com/nada

NADA: better methods are available to

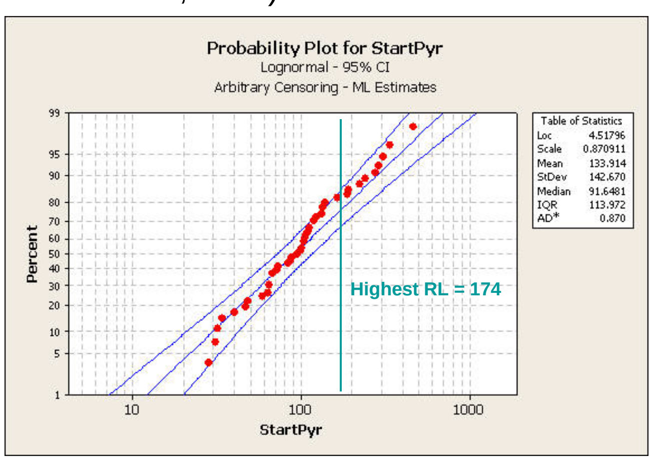
1. Estimate descriptive statistics
2. Run hypothesis tests
3. Plot data
4. Compute a regression equation

## Estimating descriptive statistics: Better methods that should be recommended today

1. MLE
   – full method, not Cohen's tables
2. Kaplan-Meier
   – nonparametric method, standard in other disciplines
3. Robust ROS
   regression on order statistics
   – regression on a probability plot

## Example censored data set

- Pyrene concentrations in benthic sediments. 56 observations, 11 censored at 8 DLs. From She (Journal AWRA, 1997)



## Estimating Descriptive Statistics

### Maximum Likelihood Estimation (MLE) -

- Input < RL as interval-censored data (0 - DL)
- Handles multiple detection limits
- Is a parametric method -- must specify distribution
- Works best for large (>50) samples with small skew.

## Maximize likelihood function L

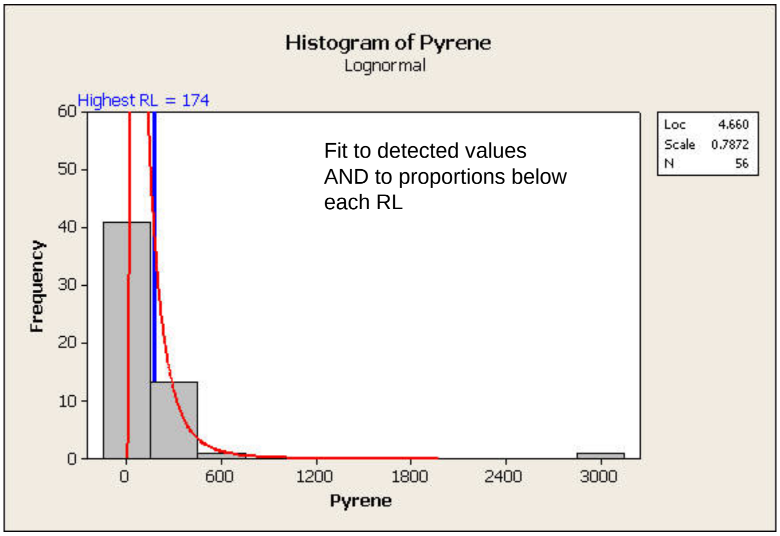
$$L = \prod p[x_i]^{\delta_i} \bullet F[x_i]^{1-\delta_i}$$

Where p is the normal pdf: $p[x] = \dfrac{\exp\left[-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2\right]}{\sigma\sqrt{2\pi}}$

F is the normal cdf: $F[x] = \Phi\left[\dfrac{x-\mu}{\sigma}\right]$

$\delta$ = 1 for detected observations and
= 0 for censored observations.

## MLE fits distribution to data




## Estimating Descriptive Statistics

First recommended method: MLE

| Method | Mean | StDev | Pct25 | Median | Pct75 |
|---|---|---|---|---|---|
| MLE(ln) | 133.9 | 142.7 | 50.9 | 91.6 | 164.9 |

Works well if data fit the assumed distribution

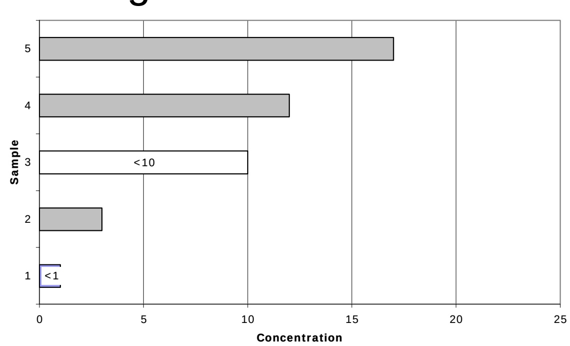
No need to substitute values for nondetects

## Estimating Descriptive Statistics

### Kaplan-Meier (Survival Analysis )

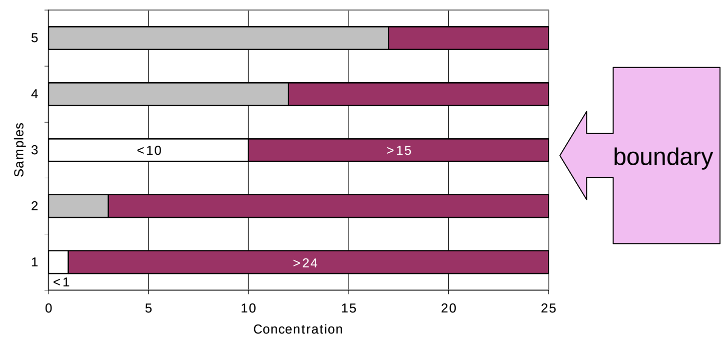
- Standard method in medical and industrial statistics
- Nonparametric. No distribution assumed.
- Count # of values above and below each detected observation.
- K-M software is hardwired for right-censored data ("greater-thans"). Our "less-thans" (X) must first be transformed into right-censored values:
  flip = Constant - X.

## Flipping: turning left-censored data into right-censored data



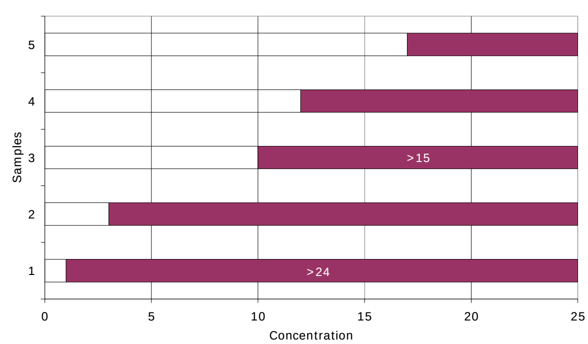

- Five observations, two nondetects ( <10, <1)
- Left censored data

## Flipping: turning left-censored data into right-censored data




- Create upper boundary > max of data. Here = 25.
- Subtract data from boundary.
- Result (red bars) are right-censored data. "Flipped data".

## Flipping: turning left-censored data into right-censored data




- Flipped Data = Large Constant - Original Data
- With software for right-censored data, use flipped values and retransform results.

## Estimating Descriptive Statistics

Kaplan-Meier   Flip to produce right-censored data

| Pyrene | FlipPyr | Flipping constant = 3000 |
|---|---|---|
| 28 | 2972 | |
| 31 | 2969 | |
| 32 | 2968 | |
| 34 | 2966 | |
| 35 | 2965 | |
| 35 | 2965 | |
| 40 | 2960 | |
| <100 | >2900 …..and so on. | |

## Kaplan-Meier (Survival Analysis )

K-M will estimate the survival function S, the probability of exceeding each of the k detected values of flip

$$S = \prod_{j=1}^{k} \frac{b_j - d_j}{b_j}$$

where b = # concentrations < = x

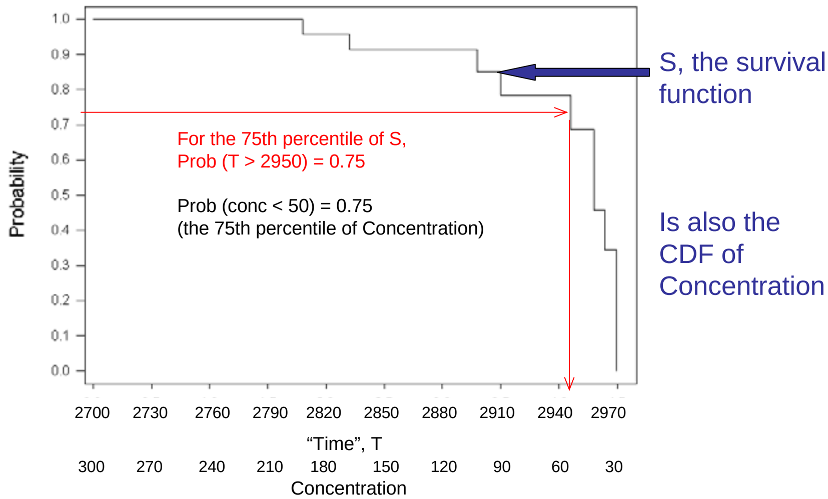
and d = # detected obs at x

S = Prob (T > flip) = Prob (< = Conc )

S is therefore the CDF (percentile function) of the original data

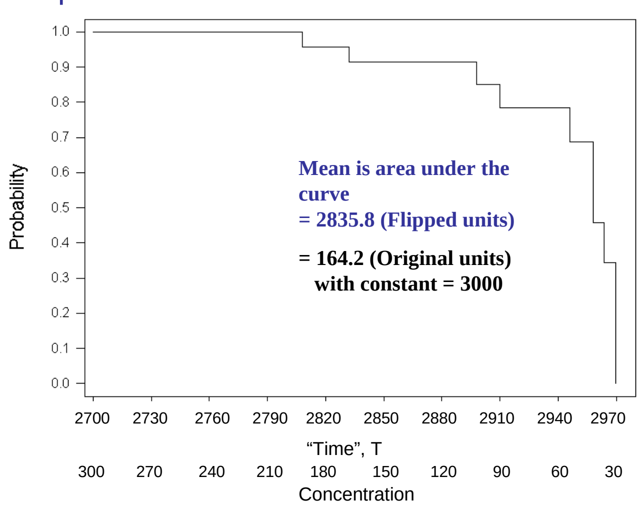
## Kaplan-Meier survival curve

Is a cdf, plotted right to left




## Estimating Descriptive Statistics

Kaplan-Meier -- estimation of the mean



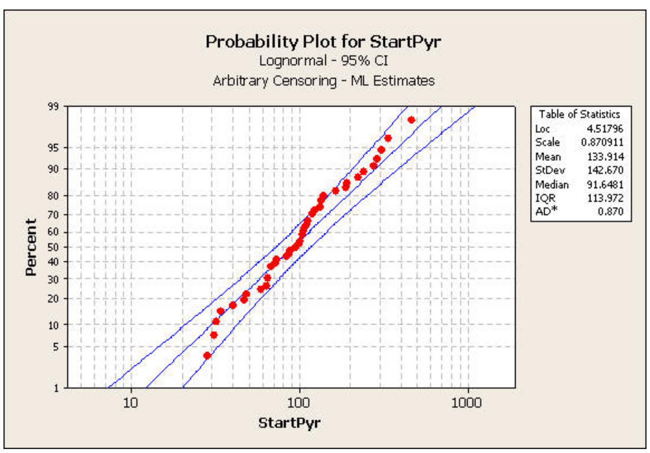
# Estimating Descriptive Statistics

Stats for Pyrene data

| Method | Mean | StDev | Pct25 | Median | Pct75 |
|---|---|---|---|---|---|
| MLE(ln) | 133.9 | 142.7 | 50.9 | 91.6 | 164.9 |
| K-M | 164.2 | 393.9 | 63.0 | 98.0 | 133.0 |

K-M assumes no distribution. Flexible

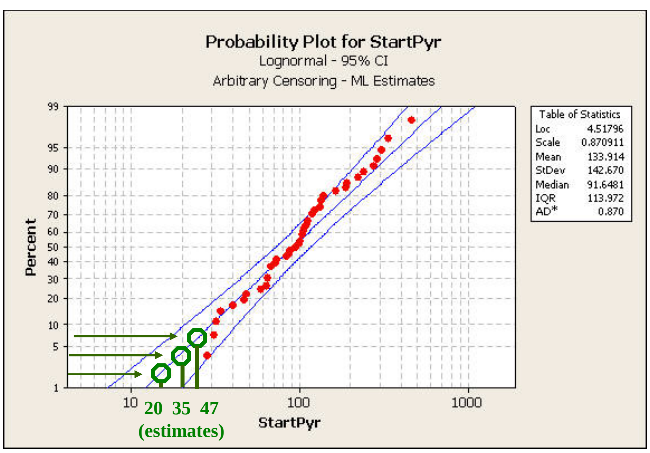
# 3. Regression on Order Statistics (ROS)



# ROS

- Calculate regression line on a probability plot.
- WRONG  Fully parametric ROS
  Intercept and slope are mean and standard deviation of the line. MLE is always better.
- RIGHT  Robust ROS. Helsel and Cohn (1988). Compute stats from detected observations plus points for nondetects picked off the regression line.

# Example – Robust ROS method



# Example – Robust ROS method

~~<25~~ ~~<35~~ ~~<50~~ 55 77 98 172 296 325

**20 35 47**

**(estimates)**

Estimated Summary Stats:

| | | | |
|---|---|---|---|
| mean | 163.2 | median | 90.5 |
| sd | 393.1 | IQR | 69.6 |

# Estimating Descriptive Statistics

## Regression on Order Statistics (ROS)

| Method | Mean | StDev | Pct25 | Median | Pct75 |
|---|---|---|---|---|---|
| MLE(ln) | 133.9 | 142.7 | 50.9 | 91.6 | 164.9 |
| K-M | 164.2 | 393.9 | 63.0 | 98.0 | 133.0 |
| ROS(ln) | 163.2 | 393.1 | 63.2 | 90.5 | 132.8 |

Robust ROS results usually similar to K-M

None of these 3 methods substitute values fabricated with a multiplier times the detection limits

None of these 3 methods substitute values fabricated with a multiplier times the detection limits

MLE

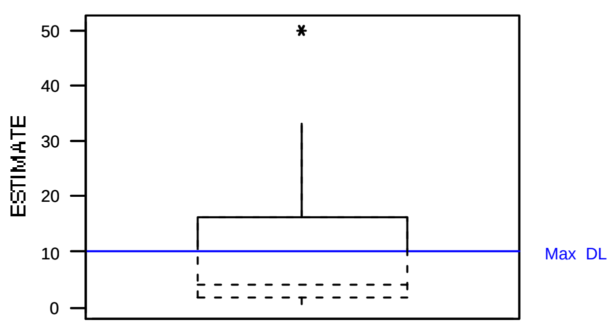
Kaplan-Meier

Robust ROS

| Method | Mean | StDev | Pct25 | Median | Pct75 |
|---|---|---|---|---|---|
| MLE(ln) | 133.9 | 142.7 | 50.9 | 91.6 | 164.9 |
| K-M | 164.2 | 393.9 | 63.0 | 98.0 | 133.0 |
| ROS(ln) | 163.2 | 393.1 | 63.2 | 90.5 | 132.8 |

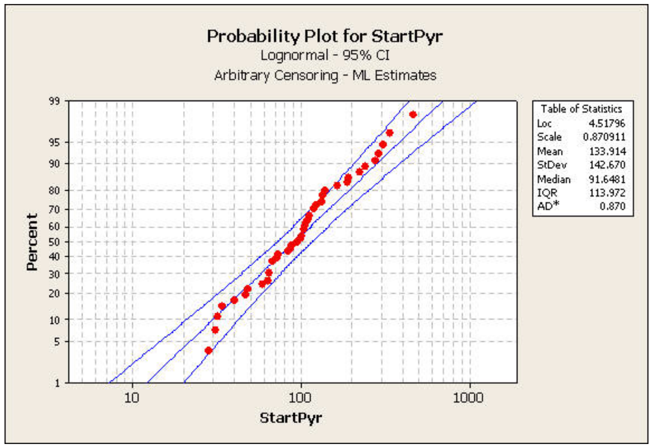
# Plotting censored data

## censored boxplot




All data below highest DL wiped off plot. Data above are same as if there were no DLs. Estimates below can be dashed in.

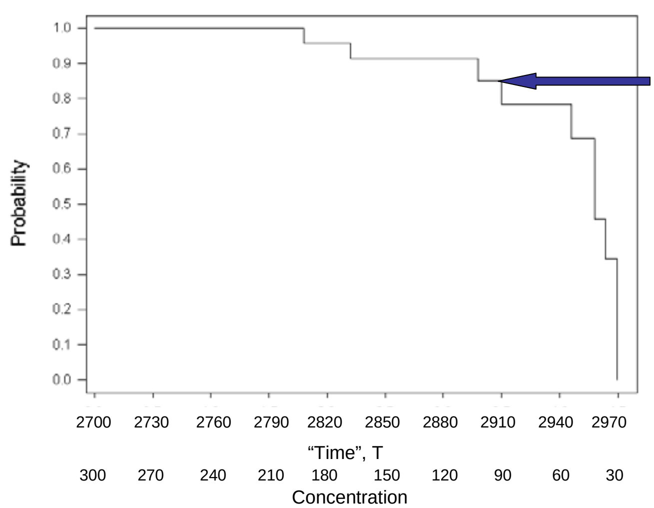
# censored probability plot




Detected observations plotted. Their percentiles (y-axis) adjusted for nondetects using K-M or robust ROS

# Survival function plot

Function drops at detected obs. Their percentiles (y-axis) adjusted for nondetects using K-M

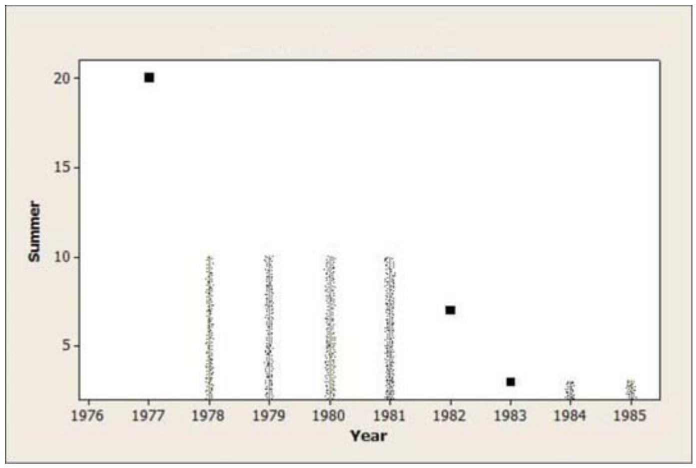



S, the survival function

Is also the CDF of Concentration

## Scatter plots

Nondetects shown as interval-censored, not as a point




<10

<1

## Hypothesis Tests for Censored Data

1. Nonparametric methods
2. Distributional (Parametric) methods

Never delete less-thans !

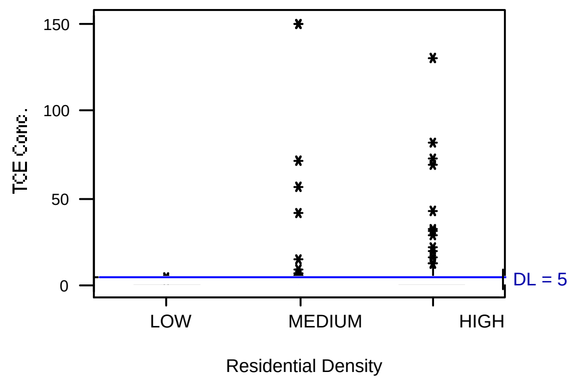
## For one detection limit

- Can always run a nonparametric test
- All nondetects are tied at lowest rank
- Proportion of ties captures low-end information
- No fabrication
- Results are unequivocal

## Testing groups with multiple DLs

- Parametric: use variation of censored regression. Coefficients estimated by MLE
- Nonparametric: Wilcoxon score tests (scores are modified ranks)

## Multiply-censored data




- TCE concentrations censored at 1, 2 and 5 ug/L

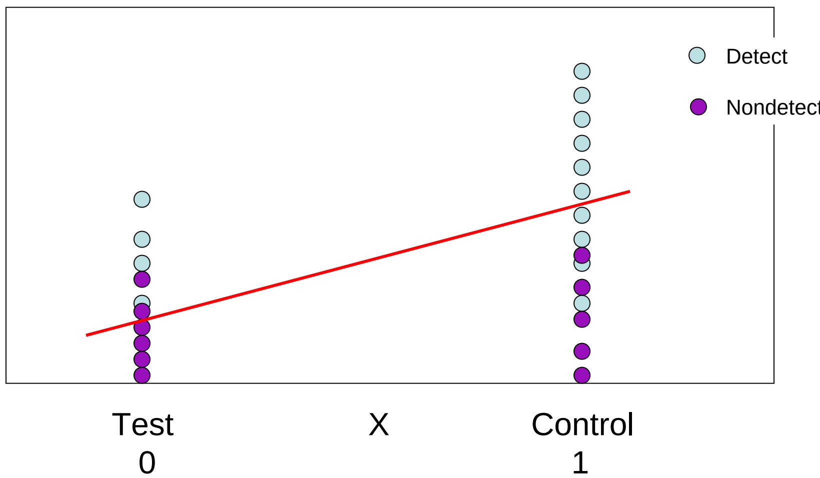
## Tests with multiple limits

Parametric
Regression of Y versus group id
to get an analog of t-tests and ANOVA

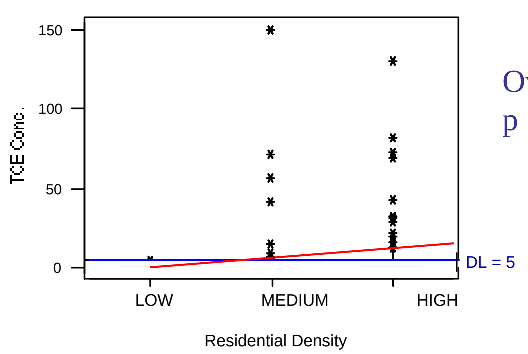
The slope is fit by MLE

Test for slope = 0 is test for diffs between means

Regression goes through mean of both groups. Is the slope ($\Delta$mean) = 0?



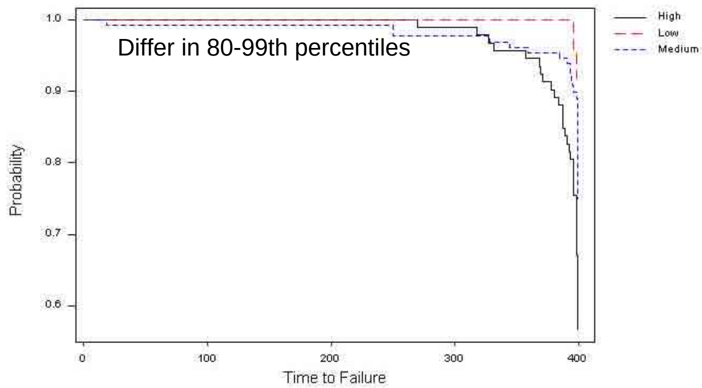

Cens. regression finds differences between means of logarithms




Overall test
p = 0.008

Individual tests: mean log of LOW ≠ HIGH

# Wilcoxon score tests
(scores are modified ranks)




Wilcoxon score test compares survival curves (cdfs).
Chi-square = 16.08   p = 0.0003

Multiple DLs no problem

# Hypothesis tests for censored data

- Substitution may give wrong results!
- For one DL, can always run nonparametric test with nondetects tied at lowest rank
- For multiple DLs
  1. censor at highest DL and run standard NP test
  2. use censored regression (parametric) method
  3. use nonparametric score tests

# Correlation and regression with censored data

1. Distributional methods

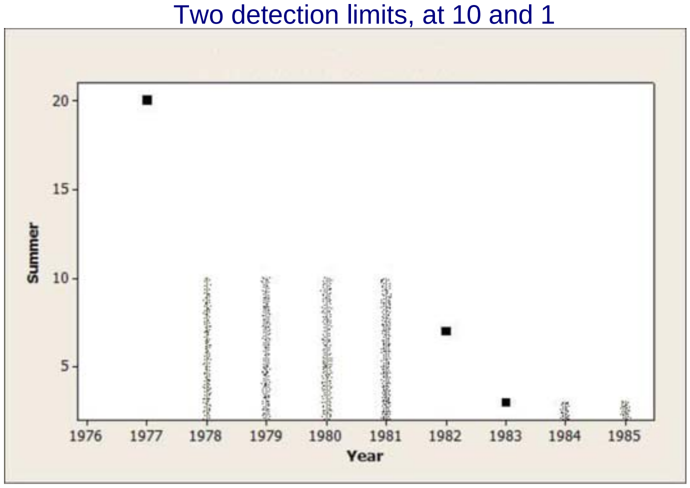
Censored regression. Issue: are residuals normal?

2. Nonparametric methods

Kendall's tau
Logistic regression
Proportional Hazards

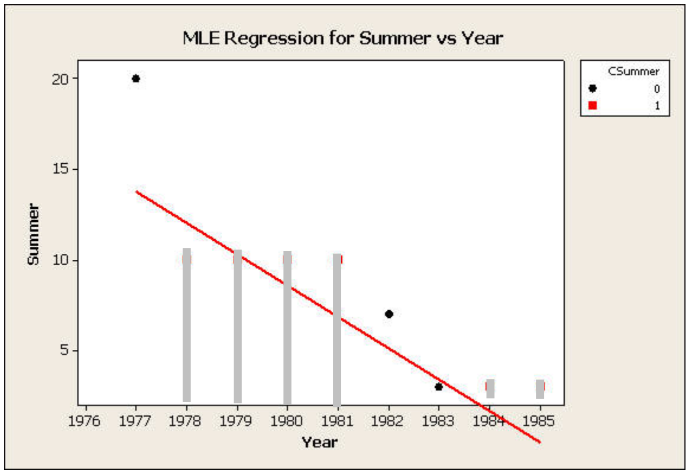
## Is there a correlation between Y and X (time)?

Is there a trend?
Two detection limits, at 10 and 1



Corr coeff. -0.75 slope -1.73

Slope is fit by MLE, using both detected values and proportions below each RL




# Correlation and regression with censored data

Parametric approach: MLE

| Summer conc | Corr coef | Slope | p-value |
|---|---|---|---|
| DL | -0.80 | -1.77 | 0.001 |
| 1/2 DL | -0.71 | -1.44 | 0.034 |
| zero | -0.46 | -1.12 | 0.216 |
| MLE | -0.75 | -1.73 | 0.000 |

## Correlation and regression with censored data

Nonparametric approach: Kendall's tau

| Summer conc | Corr coef | Slope | p-value |
| --- | --- | --- | --- |
| DL | -0.80 | -1.77 | 0.001 |
| 1/2 DL | -0.71 | -1.44 | 0.034 |
| zero | -0.46 | -1.12 | 0.216 |
| MLE | -0.75 | -1.73 | 0.000 |
| tau | -0.36 | -2.59 | 0.13 |

[different scale than r]

## Summary

Survival analysis for data with nondetects

- Methods are available for computing descriptive statistics, plots, hypothesis tests, and regression for censored data
- There are much better methods than substitution, especially for multiple RLs
- One RL can be handled with standard nonparametric methods
- Multi-RL data --use score tests/K-M methods or MLE if distribution is known

## Bottom Line

- Survival analysis methods for handling censored data are in use in the medical sciences and astronomy
- They should be used in the environmental sciences as well

# Assessing the Risk Associated with Mercury: Using ReVA's Webtool to Compare Data, Assumptions and Models

Betsy Smith, US EPA, NERL
and
Valeria Orozco, Waratah Corporation

## *Uncertainties associated with assessing Mercury risk*

- Our understanding of the methylation process in ecosystems
- The identification and spatial distribution of sensitive populations
- The spatial pattern of mercury deposition

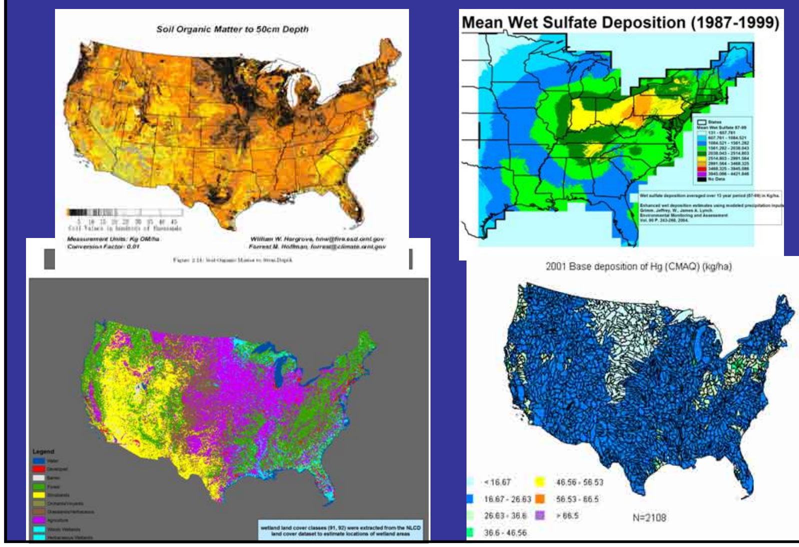
## *Methylation in ecosystems*

***(process by which Hg becomes more toxic MeHg)***

Function of

- Soil organic material
- Wet sulfate deposition
- Wetland area
- Surface water area (bioaccumulation in fish tissue)

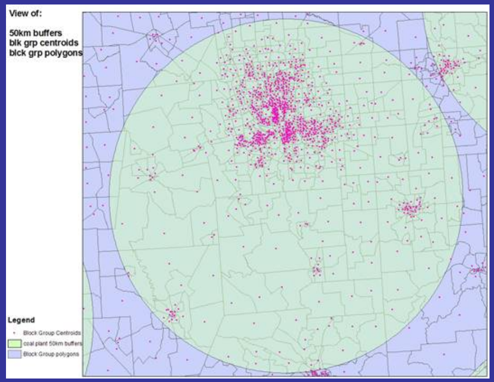
## *Components of methylation potential*



## Identification of Sensitive Populations

- Women of childbearing age (ages 16-49)
- Children (2-5 years of age)
- Middle-aged men (>40 years of age)

## Mapping Sensitive Populations

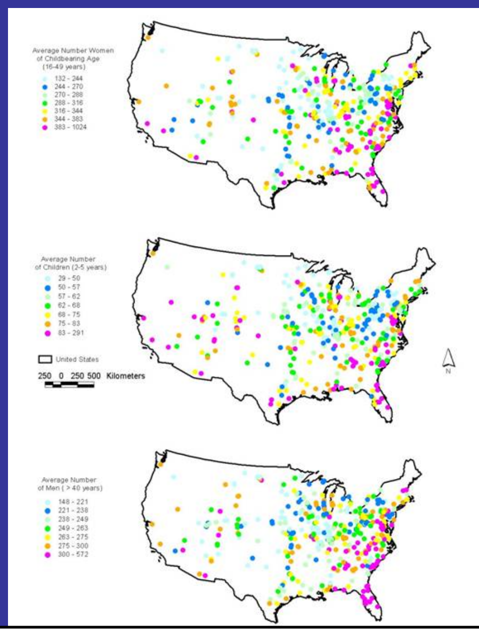



**Census 2000 used to estimate sensitive populations within 50 km buffer around EGUs. If block group fell within buffer then the population data for that block group was counted.**

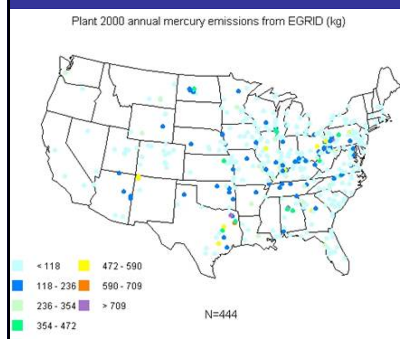
*Women of Childbearing Age*

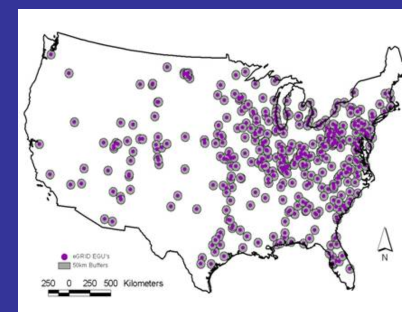
*Children*

*Middle-aged Men*




Estimating Areas of Enhanced Deposition

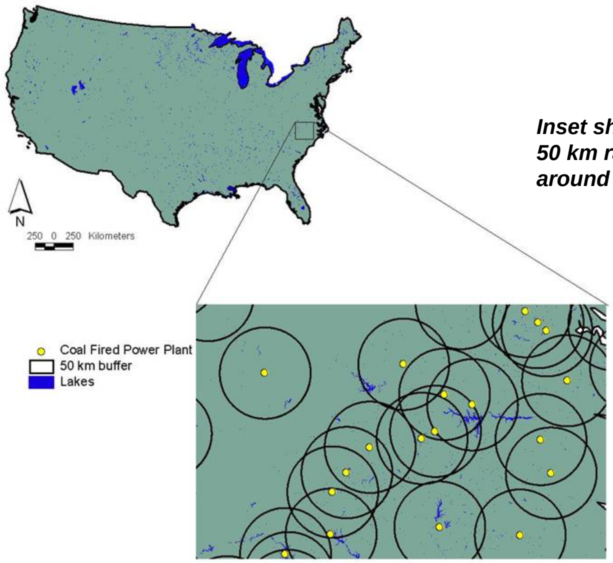


## *Quantifying Deposition of Divalent Hg*

- Used OAQPS Industrial Source Complex (ISC ) model out to radius of 50 km
- Assumed mean stack height where multiples
- Considered cumulative impact when adjacent plants overlapped deposition areas

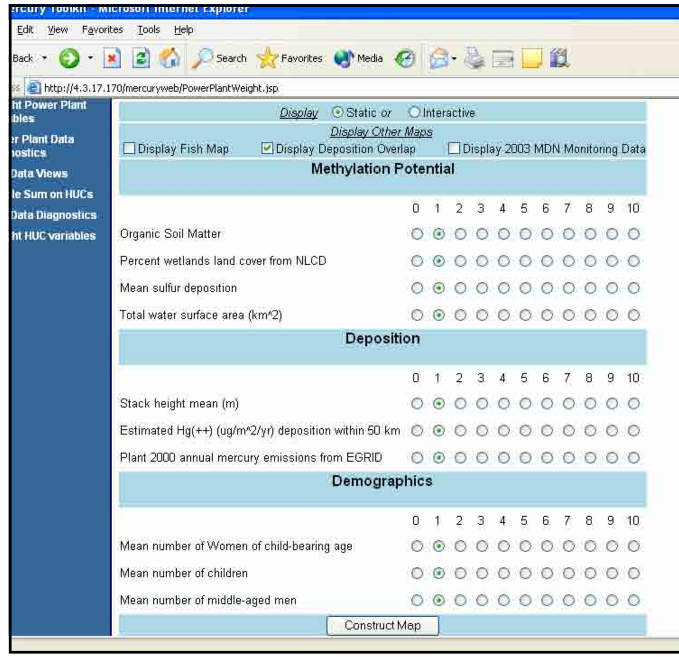
Lakes Coverage from the USGS National Hydrography Dataset



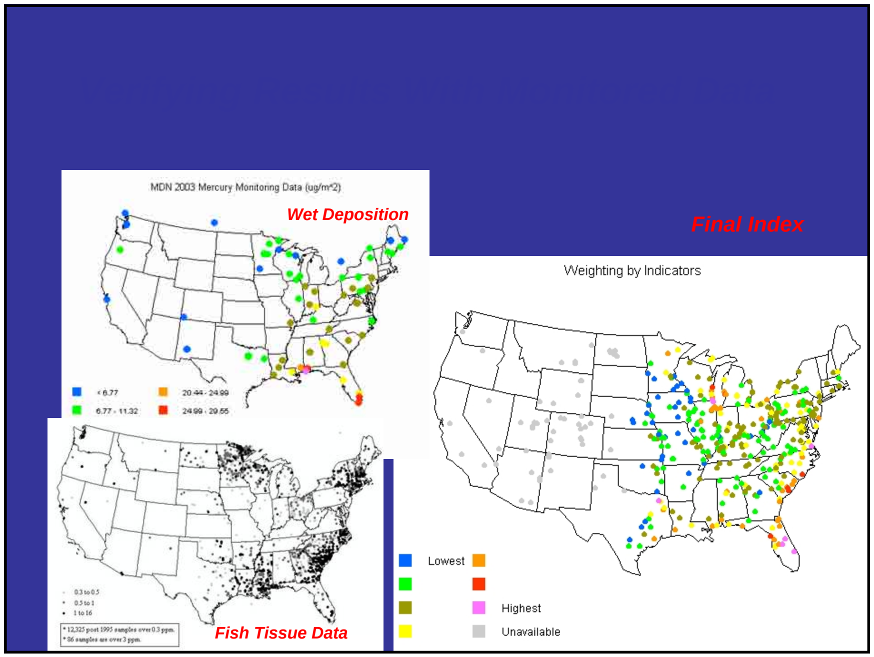

***Inset showing overlap of 50 km radius circles around EGUs***

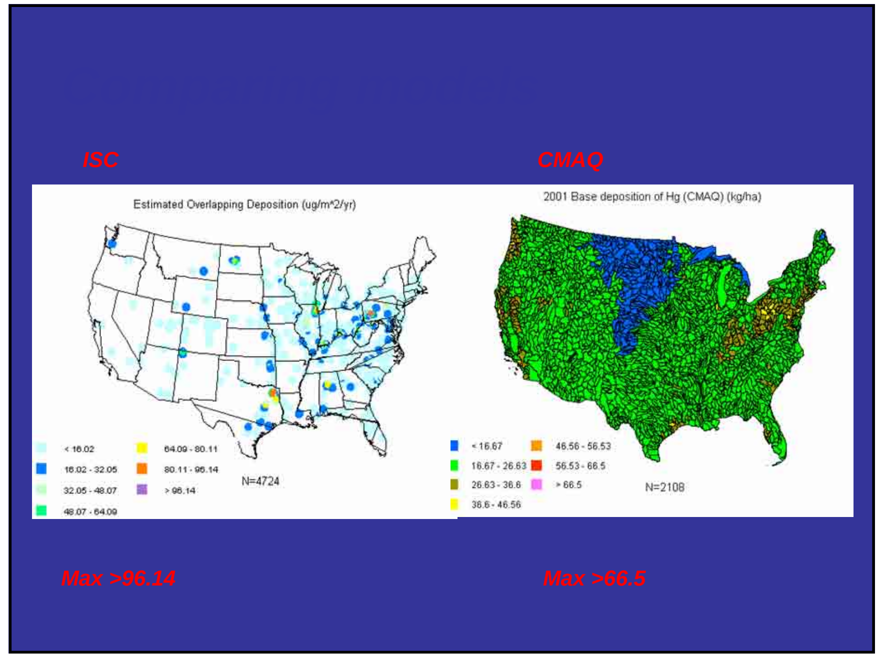
# ReVA's Hg-EDT

- Raw data can be viewed and explored
- Choices can be made as to which data or model results are used in determining overall risk
- Different weights for influential parameters can be set for estimating a methylation potential index
- Comparisons can be made between estimated and monitored data
- Sensitive populations, methylation potential, and estimated mercury deposition can be integrated into relative rankings of risk




***Creating an Index of Mercury Risk for the Country***


MDN 2003 Mercury Monitoring Data (ug/m^2)
Wet Deposition
< 6.77
6.77 - 11.32
20.44 - 24.99
24.99 - 29.55
Fish Tissue Data
Final Index
Weighting by Indicators
Lowest
Highest
Unavailable


ISC
CMAQ
Estimated Overlapping Deposition (ug/m^2/yr)
< 16.02
16.02 - 32.05
32.05 - 48.07
48.07 - 64.09
64.09 - 80.11
80.11 - 96.14
> 96.14
N=4724
2001 Base deposition of Hg (CMAQ) (kg/ha)
< 16.67
16.67 - 26.63
26.63 - 36.6
36.6 - 46.56
46.56 - 56.53
56.53 - 66.5
> 66.5
N=2108
Max >96.14
Max >66.5

## Comparing Risk from Different Size Power Plants

| Score | Large (>0.25 tons) | Medium (0.11-0.25 tons) | Small (0.001-0.11 tons) | Total |
|---|---|---|---|---|
| 0 - 3 | 0 | 0 | 0 | 0 |
| 4 - 9 | 6 | 14 | 40 | 60 |
| 10 - 13 | 14 | 22 | 75 | 111 |
| 14 - 16 | 23 | 37 | 90 | 150 |
| 17 – 20 | 11 | 21 | 85 | 117 |
| Total | 54 | 94 | 290 | 438 |

## To see more:

http://4.3.17.170/mercuryweb

Username: datahg

Password: t1met0g0 (ones and zeros)

# EPA Infrastructure for Ambient Air Bias Traceability to NIST

Changes and Status

Mark Shanis, OAQPS

San Diego, 2005

# GOAL:STRONGER REGIONAL SUPPORT

FOCUS ON 3 PROGRAMS

EPA NPAP: MAILED (?PSD) + MOBILE TTP

SRP: 2 UPGRADES, BASE IN LV

PROTOCOL GASES VERIFICATION: 3RD PARTY

# NPAP(M+TTP) + PEP = NPEP

- 2003 TRANSITION: Mailed Only, Back of the Analyzer (BOA) to Mailed(R1,2,3,8,9,10)+Mobile Through-the-Probe (TTP)/Station Inlet (3~used)
- 2004,Transition continues: Mailed (Same 2003) +TTP
- May 2004:1st group training and certification, Like PEP (Written+ Hands-on): R2,4-7,9
- SOP (Adding to Draft as Use) and Implementation Plan (still in Prep).
- New:Reg2 Hi Flow Rate Subsystem (May-June)

# 2004(+3Mos.) NPEP 1sts: Status/Accomplishments

EPA SOP Development (MBS+ 6Regions)

- Staff /SOP Training Development; 2 Sessions in ’04;Class+Hands on; Certs.
- EPA Tow Vehicle/Trailer Training (C+HO)
- Table of PEs and ESAT Costs; 5 Regns-2 EPA,3 ESAT; 2New R; TTP 1st, TTP+PEP
- Reg.2 Study: Hi Sampling Flow Rate Sites
- Reg 9 TTP/CARB TTP,LT 5%;Other QA Cks

## *SUMMARY OF THROUGH-THE-PROBE AUDITS IN 2004*

| *Region* | $O^3$ | CO | $SO^2$ | $NO^2$ | Total # of Audits for each Region | $$ (K=1000) |
|---|---|---|---|---|---|---|
| ***1*** | | | | | **0** | **5 (1x trng,1FS)** |
| ***2*** | | | | | **0** | **10(1xtrng,2FS)** |
| ***4**** | 24 | 2 | 6 | 1 | **33** | **35(3xtrng,2FS)** |
| ***5*** | 32 | | | | **32(EPAonly)** | **(35; -12 for training, 2x)** |
| ***6**** | 16 | 9 | 8 | 9 | **42** | **35 PE; 6.4 Trng, 3x** |
| ***7*** | 15 | 2 | 3 | 1 | **21(EPAonly)** | **(25 MOU)** |
| ***9**** | 32 | 13 | 4 | 9 | **58** | **30 PE+8.3Trng, 3x,1;2x,2)** |
| ***10*** | | | | | **0** | **5(2xtrng, 1)** |
| **Total Audits for all Regions** | **119** | **26** | **21** | **20** | **186** | *Est$/PE~=1.7 |

| TTP COMPARISON: REGION 9 & CARB:: | | |
|---|---|---|
| **AUDIT LEVEL** | **RPD CARB** | **RPD EPA** |
| ***O3*** | | |
| **High** | **-1.7** | **0.952** |
| **Mid** | **-2.8** | **0.930** |
| **Low** | **-2.9** | **0.638** |
| ***CO*** | | |
| **High** | **-5.2** | **-4.64** |
| **Mid** | **-1.6** | **-0.07** |
| **Low** | **2.9** | **7.13** |
| ***SO2*** | | |
| **High** | **-3.3** | **-6.27** |
| **Mid** | **-3.2** | **-6.05** |
| **Low** | **-2.9** | **-4.01** |
| ***NO2*** | | |
| **High** | **-4.3** | **-0.22** |
| **Mid** | **-5.2** | **-0.03** |
| **Low** | **-5.5** | **0.34** |

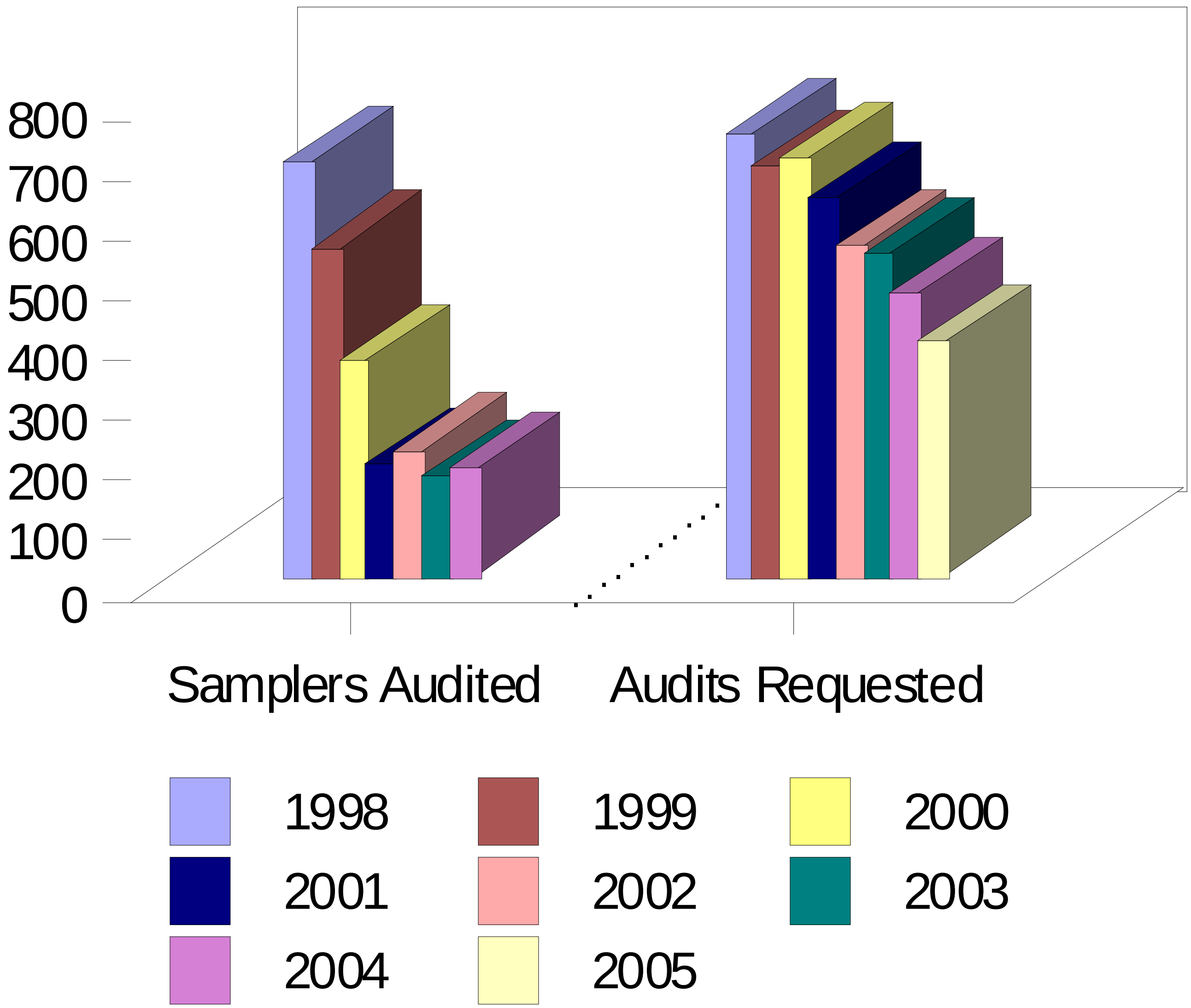
# Combination Benefits/TradeOffs

- If EPA Staff Do Audits: No ESAT Labor Costs
- If ESAT Staff Do Audits: Only EPA training, Oversight Time Needed
- Common Benefit: Expanded Resources, Can Do Both TSAs and PEs more easily
- 04:EPA R5,7-TTPonly;ESATR4,6,9-NPEP
- 05:6Labs do 9Regs.;Min.Mailed+TTPin 5R

# Mailed Program, Reductions

- Mailed Contractor Funded in 04'(all) and '05(partial mix) for Regions 1,2,3,8,9, and 10
- Provide in 04'&'05: Ozone, CO, SO2, NO/NO2, PM10, Lead; No PAMS,PSD
- 04/05 Buy-ins; TTP Certs. in '05
- Max # Mailed PE Devices Now Very Limited: 20→?15 O3,5-6 CO/SO2/NO/NO2; 10 PM10
- 05:Approx $215K for Mailed; app.$315K for TTP
- Next Yr Funding? IMPT: S&L OK 103 use

## US SLAMS/PSD Ozone Monitors Audited by NPAP



## US SLAMS/PSD OZONE Monitors Audited by NPAP (as of 3-24-05)

| Year | **No. of Samplers Audited**/ No. Agencies (=Shipments) | **No. of Audits Requested**[1]/ No. of Agencies Requesting |
|---|---|---|
| 1998 | **686**/188 | **727**/188 |
| 1999 | **542**/184 | **674**/201 |
| 2000 | **352**/80 | **692**/202 |
| 2001 | **183**/55 | **623**/164 |
| 2002 | **205**/57 | **544** /136 |
| 2003 | (137 mailed + 22 ttp) = **159**/29 | **533** /132 |
| 2004 | (54 mailed + 119 ttp) = **173**/17 | **463**/114 |
| 2005 | 0/3 | **386**/102 |

# Summary of Through the Probe Audits Scheduled for 2005

| Region | $O_3$ | CO | $SO_2$ | $NO_2$ | Total Audits for each Region | $$=ESAT+EPA, K=1000 |
|---|---|---|---|---|---|---|
| **1** | 11 | 2 | 1 | 7 | **21** | **15** |
| **2** | 15 | 6 | 9 | 10 | **40** | **40+?5-10** |
| **3** | 9 | 8 | 9 | 7 | **33** | **15** |
| **4** | 18 | 5 | 5 | 6 | **34** | **40+3** |
| **5** | | | | | **24?** | **22+8** |
| **6** | 20 | 8 | 4 | 15 | **47 (+8T)** | **45** |
| **7** | 12*+30 | 4 | 1*+ 6 | 2*+5 | **15*+45** | **28+MOU 25** |
| **9** | 24 | 19 | 8 | 13 | **64** | **35** |
| **10** | 12 | 14<br>**7of 14<br>mailed | 3 | 4 | **33** | **25** |
| **Total Audits for all Regions** | **151?** | **66** | **46** | **69?** | **332?** | ?281(+54)+25 |

**T = Tribes (paid for by tribes)**
***   TTP PE's already completed**
**** Mailed TTP**

# NPEP Summary

- Special Advantages:
  - Mobile:Timeliness, Tighter Accuracy, Troubleshooting
  - Mobile Lab Multi-functionality Designed in: Audits; Sampling Priorities; Certifications
  - Enhanced Equipment and labor, Regionally-Based, making it easier to do PEs and TSAs, and High Priority Sampling, Training, and Support for New Methods for S&Ls in Region
  - NPEP Flexibility with M+ TTP:Mailed can do inaccessible, 1-2 monitor sites, BOA or TTP; Mobile Lab can go in if Mailed indicates problem

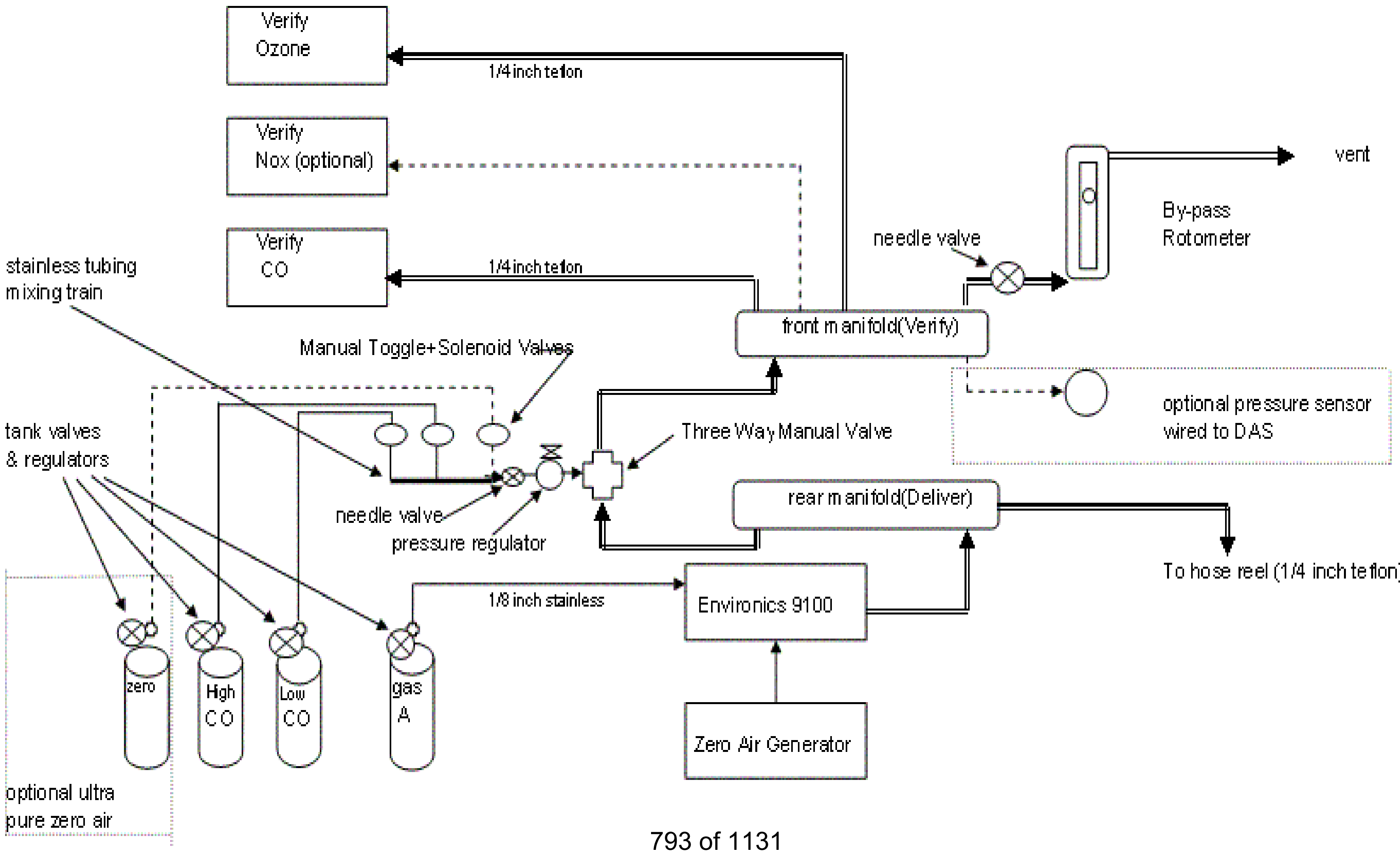
# NPEP Summary (cont'd.)

Issues: Funding Future?

Urgent need to communicate pilot $/PE,flex.

- To Convince S&L to Give 103/105 OK in'06
- Can't Rollover Replacement Cost Fund Using EPA Program Funds. EPA Program Funding much less certain than STAG
- Can Rollover with STAG 103 or 105 funds
- Hi Flow Stations, Portability; PG?,PAMS; Data Base System for Past NPAP and Future; PSD

# CAN 1 PERSON DO IT?



# Region 7 Mobile TTP Audit Lab

# Roof Platform+Sampling Mods.

# TEOM Mod +PC,etc.

# Interior Front, Sampling Mod.

# EPA/NIST SRP Network

- STATUS
  - In Regions 1, 2, 4, 5, 6, 7, 8 and 9; 2 does 3, 9 does 10; a 2nd in 9 Reg.9Lab
  - 2 originally set up for comparing the 8 Regional SRPS to NIST,1 traveling, 1stationary;1st based in RTP; now in LV
  - Range of Ages:1st RTP, Done 2/83, last in KC, KS(R7)1/89
  - NIST has 12 Worldwide, latest made this year

# EPA SRP Network Changes

- 2 hardware and software upgrades done, with 1 exception
- Feature Improvements: Change from all Manual operation to ability to automatically perform and record required documented procedure
- Benefits- Easier to certify multiple primary or transfer standards, more consistently, and with lower zero signal
- ORIA-LV Improved Trouble-shooting; Working on Grp OK to Std. Cert. Forms, Summary Rpts.

# NIST SRP Network Changes

- NIST Talk at June ‘04AWMA mtg-provided first documentation of international comparisons, including EPA network
- Plans in progress to have BIPM(France) Lead as European Center and for non-USA SRP support
- Cost of new SRP Rising (Approx. $65K now); Revised Manual in Progress

# EPA Traceability Protocol

- On EPA TTN/EMC; for source and ambient levels, as of 98
- Presentation at this meeting
- ORD Verification Program stopped mid90s
- Users reporting problems; EPRI and EPA have done studies recently to assess problems
- Some Vendors have requested restart of Verification

# 3rd Party Verification

- Critical Features of ORD Audit Program
  - Low Cost
  - Very Low number of samples
  - Audit Sample Buying unknown to Vendor
  - Experienced Lab analysis; Vendors Coded
  - Process independent of vendors
  - RESULTS REPORTED TO PUBLIC
  - Documented Improvement in Tag Accuracy

# Bias Traceability Summary

- Programs are still active, changes occurring; Cited in Proposed 40 CFR Part 58 Revision
- Quality Data Requires both Continuation of Support and Change to keep up with Method and Data Priority changes
- Protocol Verification Success Indicates High sample numbers are not the only determinant of Effect:
  - Users and Vendors Respond to the Attention Brought by Open Bias Assessment

# Using the Through The Probe Laboratory at Sites With Large Sampling Manifolds

By

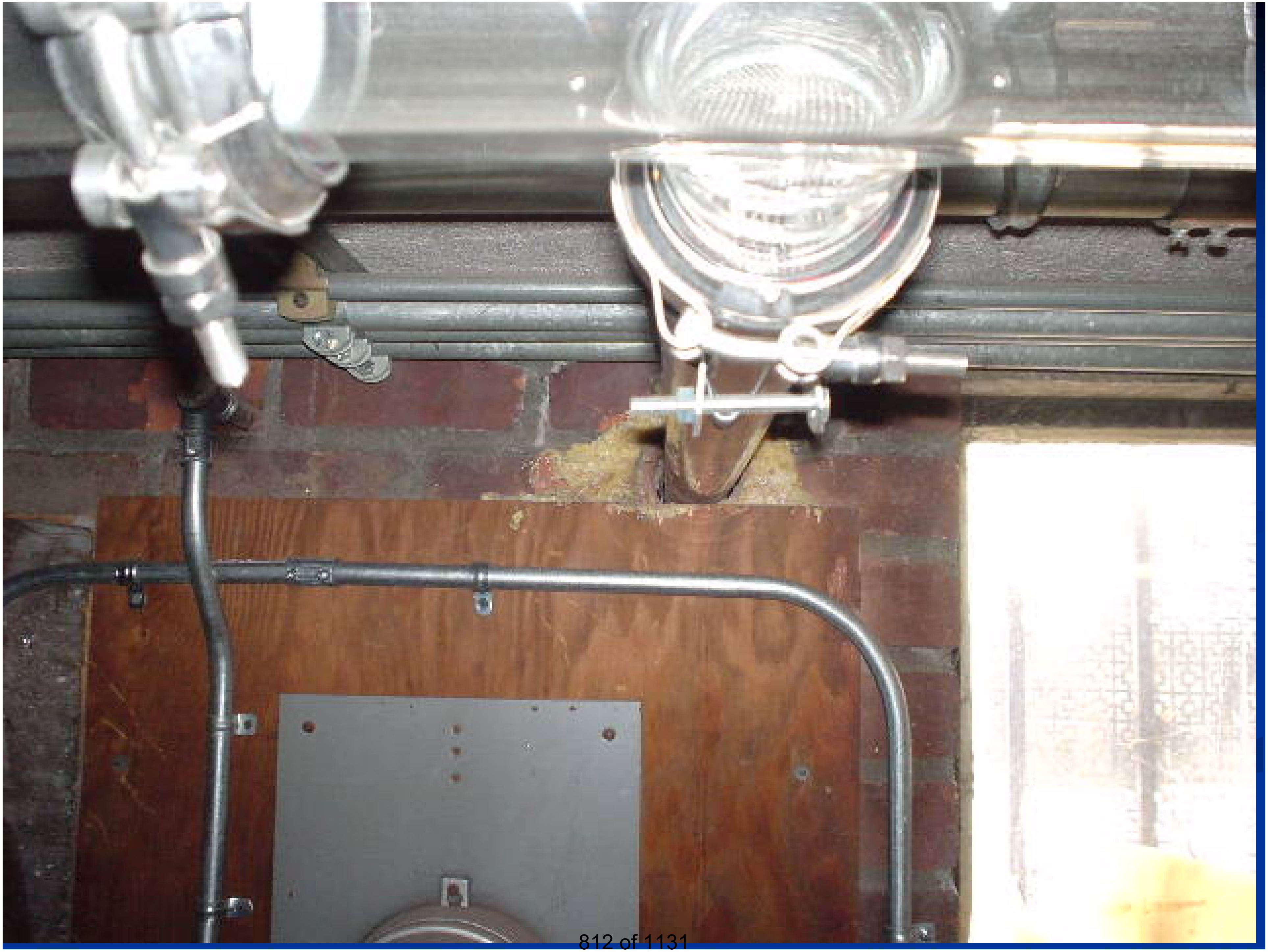
Avraham Teitz, Mark Shanis, Mustafa Mustafa, and Mark Winter

# Manifolds in Region 2

- Common manifold for all analyzers – analyzer hook up by individual ¼” Teflon pigtails
- Manifold constructed of borosilicate glass
- Variety of sizes – 1”, 2”, 3”, 4”
- Flow volumes typically 15-40 liters/minute
- Use of a blower motor or vacuum pump to generate air flow


Turn OFF
When Not
Using


GE Capital Modu
516 752-9
805553




FIRST AID


RI Department of Environmental Management
RI Department of Health
East Providence Air Monitoring Site

# TTP Laboratory Trailer Interface

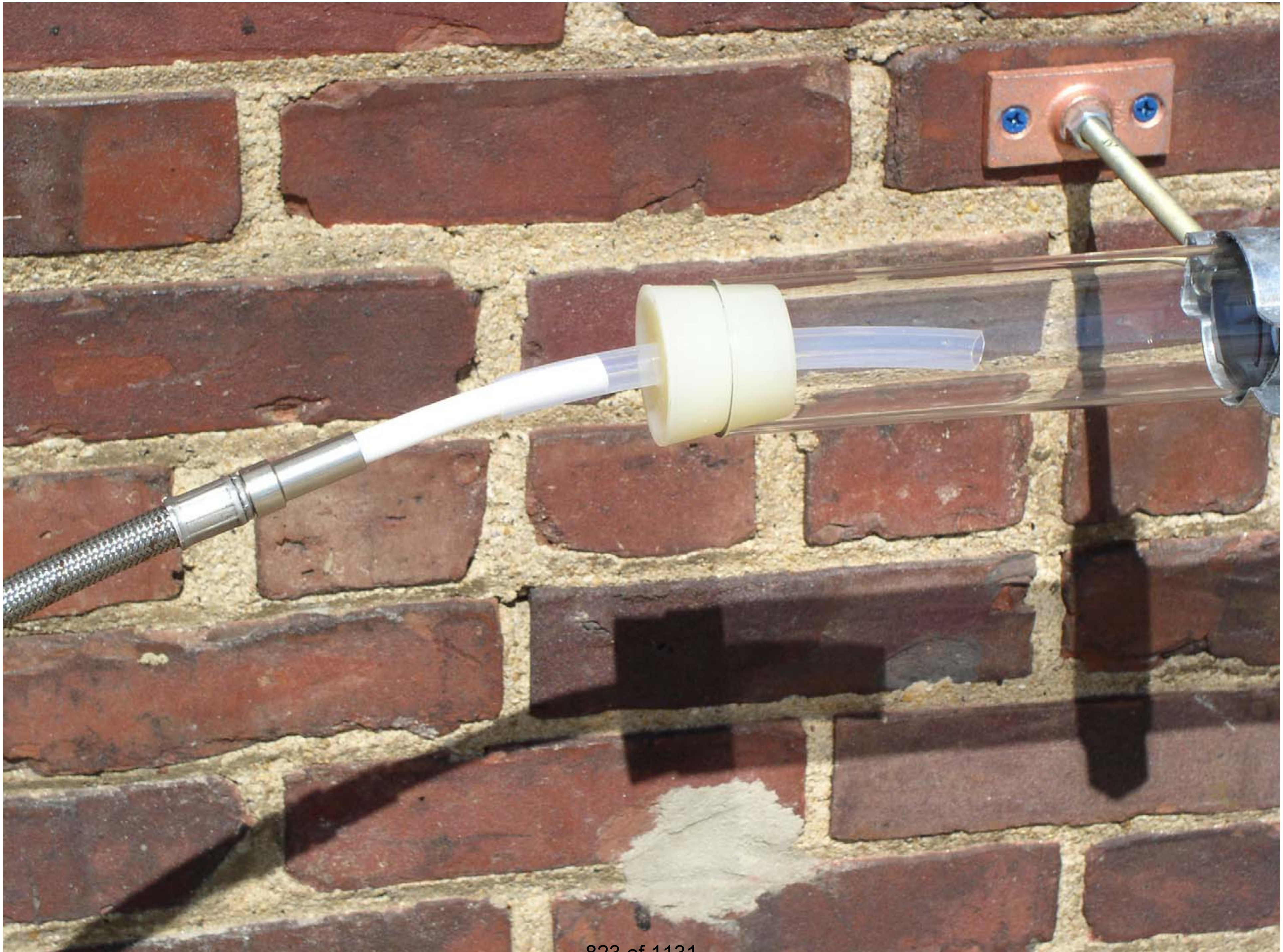
- ½” o.d. Teflon lined steel jacketed presentation line – 150’ in length
- Maximum flow rate of 14.5 liters/minute

# Problems adapting TTP Laboratory to Region 2 Manifold Systems

- Adapting ½" o.d. presentation line to glass manifolds of various sizes
- Insufficient sample flow from TTP risks burnout of blower motors or negative pressure in manifold
- 14.5 liters/minute TTP flow results in excessive residence times – outside EPA specification of 20 seconds

# To address TTP/Region 2 Issues:

- Region 2 constructed a 2” Glass manifold
- Adapted presentation line to manifold using silicone stoppers
- Attached suite of CO, $NO_x$, $SO_2$, and $O_3$ analyzers to the manifold with ¼” pigtails
- Conducted TTP audits of the analyzers and compared the results of using the manifold vs. plugging in to the back of the analyzers




DESA-MAB


EXIT
DANGER
EXPLOSIVES
KEEP AWAY

# Experimental Procedure

- TTP to provide $O_3$, $SO_2$, CO, and $NO_x$
- Presentation line connected to analyzers via manifold
- Presentation line connected directly to back of analyzers - with a tee to vent to atmosphere
- Examine the differences in analyzer accuracy when connected to the manifold vs. connection at the back of analyzer


Environics
Thermo Environmental Instruments
Thermo Environmental Instruments

# Ozone Results

| Glass Manifold | | | Back of Analyzer | | | |
|---|---|---|---|---|---|---|
| TTP Ozone (ppm) | Station Ozone (ppm) | % Difference | TTP Ozone (ppm) | Station Ozone (ppm) | % Difference | Difference in % Difference |
| 0.000 | 0.000 | | 0.000 | 0.000 | | |
| 0.420 | 0.418 | -0.5% | 0.422 | 0.421 | -0.2% | -0.3% |
| 0.186 | 0.184 | -1.2% | 0.186 | 0.187 | 0.3% | -1.5% |
| 0.074 | 0.074 | 0.1% | 0.074 | 0.074 | -0.3% | 0.4% |
| 0.000 | 0.000 | | 0.000 | 0.001 | | |

# Sulfur Dioxide Results

| Glass Manifold | | | Back of Analyzer | | | |
|---|---|---|---|---|---|---|
| TTP $SO_2$ (ppm) | Station $SO_2$ (ppm) | % Difference | TTP $SO_2$ (ppm) | Station $SO_2$ (ppm) | % Difference | Difference in % Difference |
| 0.000 | 0.000 | | 0.000 | 0.000 | | |
| 0.402 | 0.403 | 0.4% | 0.402 | 0.403 | 0.4% | 0.0% |
| 0.190 | 0.189 | -0.3% | 0.190 | 0.189 | -0.3% | 0.0% |
| 0.076 | 0.075 | -0.7% | 0.076 | 0.074 | -2.0% | 1.3% |
| 0.002 | 0.000 | | 0.002 | 0.000 | | |

# NO Results

| Glass Manifold | | | Back of Analyzer | | | |
|---|---|---|---|---|---|---|
| TTP NO (ppm) | Station NO (ppm) | % Difference | TTP NO (ppm) | Station NO (ppm) | % Difference | Difference in % Difference |
| 0.004 | 0.000 | | 0.004 | 0.000 | | |
| 0.417 | 0.418 | 0.3% | 0.417 | 0.425 | 2.0% | -1.7% |
| 0.270 | 0.271 | 0.3% | 0.270 | 0.277 | 2.5% | -2.2% |
| 0.166 | 0.167 | 0.6% | 0.166 | 0.169 | 1.8% | -1.2% |
| 0.084 | 0.082 | -2.3% | 0.084 | 0.083 | -1.1% | 1.2% |
| 0.004 | 0.000 | | 0.004 | 0.000 | | |

# $NO_x$ Results

| Glass Manifold | | | Back of Analyzer | | | |
|---|---|---|---|---|---|---|
| TTP $NO_x$ (ppm) | Station $NO_x$ (ppm) | % Difference | TTP $NO_x$ (ppm) | Station $NO_x$ (ppm) | % Difference | Difference in % Difference |
| 0.004 | 0.000 | | 0.004 | 0.000 | | |
| 0.417 | 0.418 | 0.3% | 0.417 | 0.425 | 2.0% | -1.7% |
| 0.270 | 0.273 | 1.0% | 0.270 | 0.277 | 2.5% | -1.5% |
| 0.166 | 0.167 | 0.6% | 0.166 | 0.169 | 1.8% | -1.2% |
| 0.084 | 0.083 | -1.1% | 0.084 | 0.083 | -1.1% | 0.0% |
| 0.004 | 0.000 | | 0.004 | 0.000 | | |

# $NO_2$ Results

| Glass Manifold | | | Back of Analyzer | | | |
|---|---|---|---|---|---|---|
| TTP $NO_2$ (ppm) | Station $NO_2$ (ppm) | % Difference | TTP $NO_2$ (ppm) | Station $NO_2$(ppm) | % Difference | Difference in % Difference |
| 0.001 | 0.001 | | 0.001 | 0.000 | | |
| 0.327 | 0.328 | 0.4% | 0.328 | 0.337 | 2.7% | -2.3% |
| 0.179 | 0.182 | 1.5% | 0.179 | 0.185 | 3.5% | -2.0% |
| 0.077 | 0.078 | 1.1% | 0.079 | 0.078 | -0.7% | 1.9% |

# Carbon Monoxide Results

| Glass Manifold | | | Back of Analyzer | | | |
|---|---|---|---|---|---|---|
| TTP CO (ppm) | Station CO (ppm) | % Difference | TTP CO (ppm) | Station CO (ppm) | % Difference | Difference in % Difference |
| 0.2 | 0.3 | | 0.2 | 0.3 | | |
| 39.9 | 41.6 | 4.2% | 39.9 | 41.4 | 3.7% | 0.7% |
| 18.8 | 19.5 | 3.5% | 18.8 | 19.3 | 2.6% | 0.9% |
| 7.5 | 8.3 | 11.1% | 7.5 | 8.6 | 14.4% | -3.3% |
| 0.2 | 0.8 | | 0.2 | 0.9 | | |

# Significant Findings

- Back of the analyzer results tended to be higher than manifold results
- Differences were typically in the 1-2% range

# Caveats

- Initial equilibration of the manifold system took 2.5 hours
- Possibility of error induced by constant switching of presentation line from manifold to back of analyzer
- CO station analyzer zero drift could have compromised lowest comparison point for the CO comparison

# Conclusions

- TTP Laboratory is suitable for audits of large manifold based systems
- Differences between manifold audits and back of the analyzer audits are typically in the 1-2% range
- Acceptance criteria for manifold audits may have to be "stretched" to account for this variability
- Further study to quantify the variability between the manifold and the back of analyzer sample delivery is warranted